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On the design and evaluation of adjustable footwear for the prevention of diabetic foot ulcers

Reints, Roy

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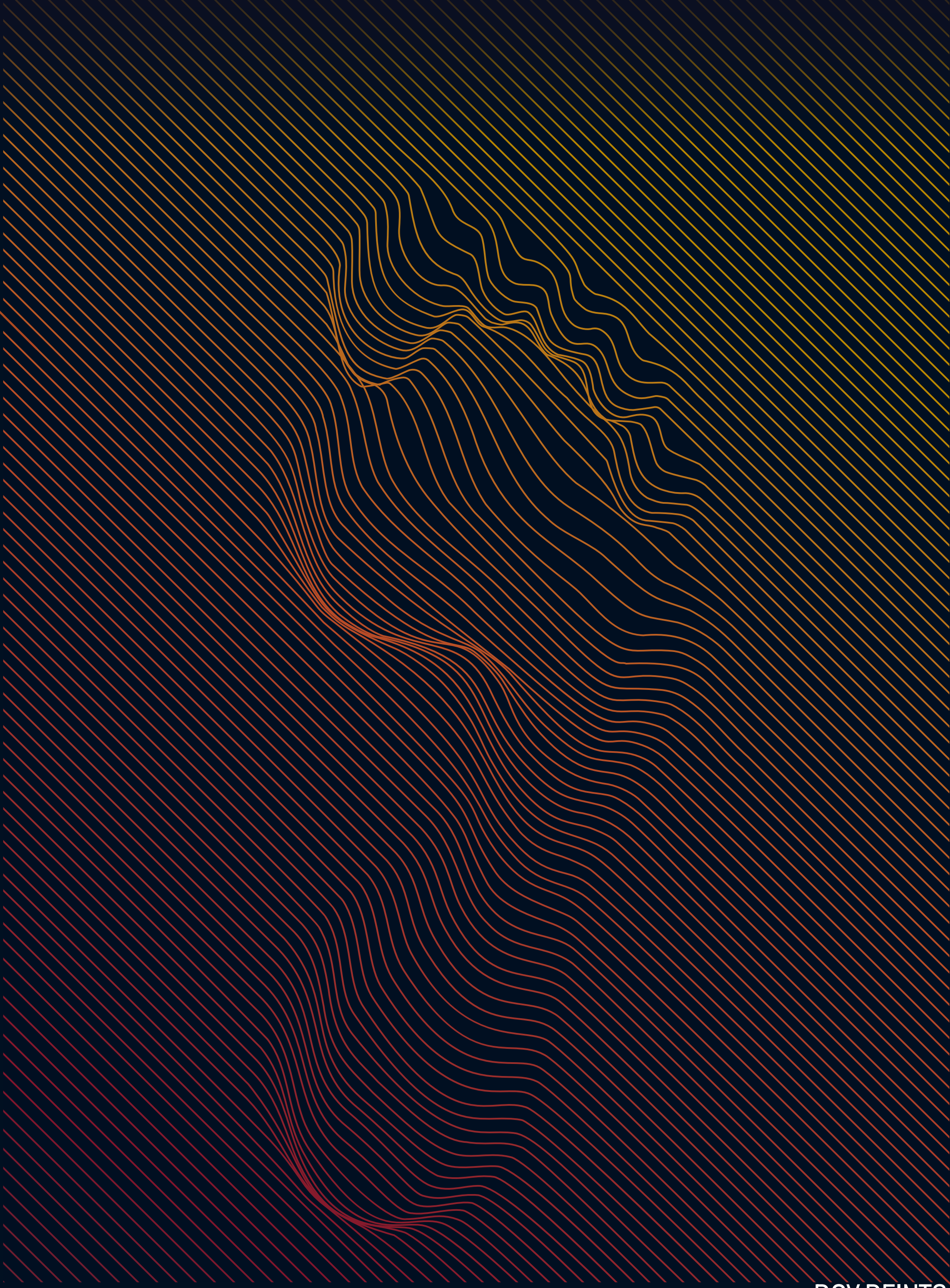

ROY REINTS

ON THE DESIGN AND EVALUATION OF ADJUSTABLE FOOTWEAR FOR THE PREVENTION OF DIABETIC FOOT ULCERS

Roy Reints

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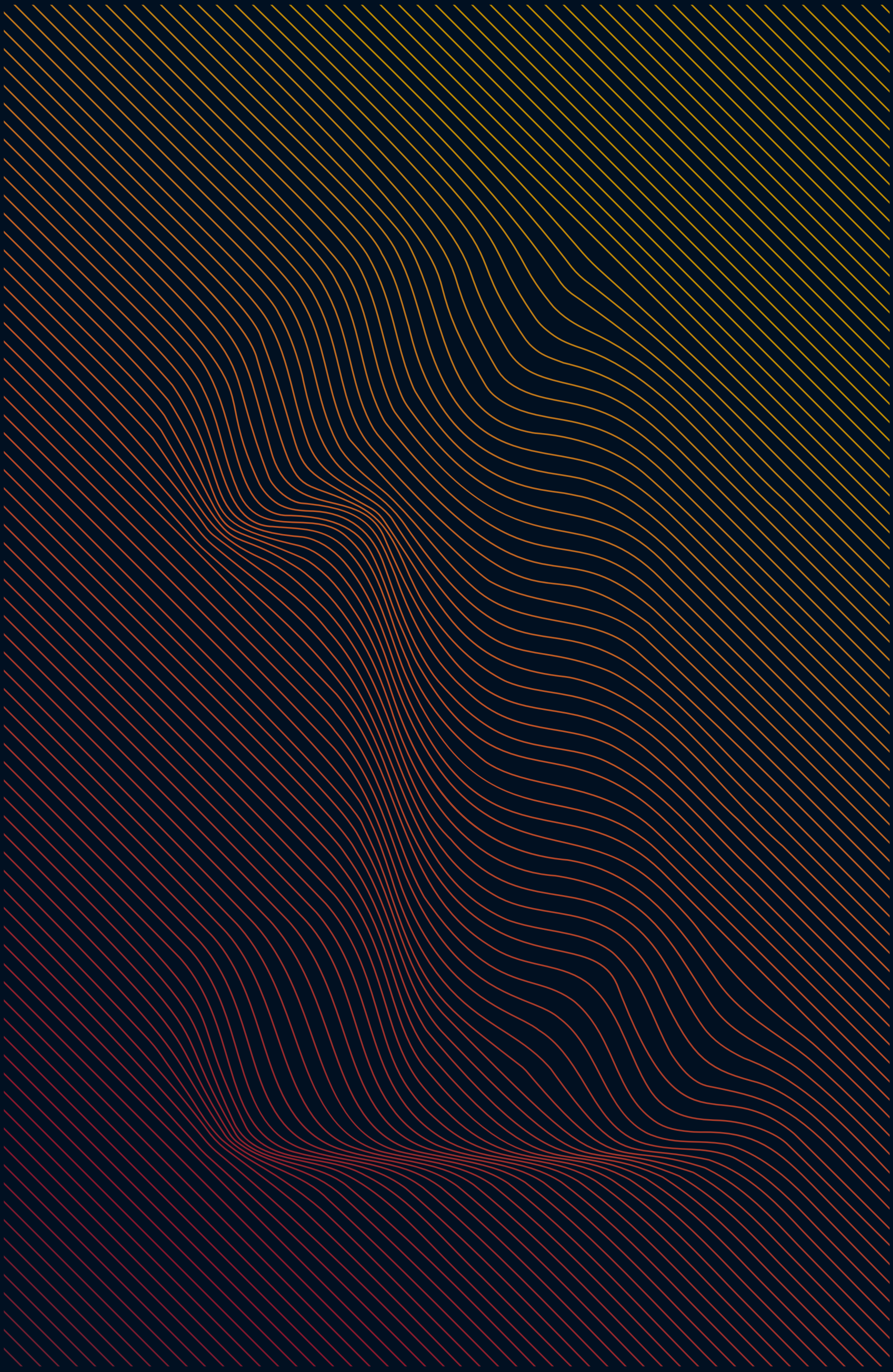

GENERAL INTRODUCTION

1

Background

Diabetic foot ulcers

Worldwide there were over 422 million people with diabetes in 2014 and this number is expected to rise[1]. Between 25% and 34% of all people with diabetes will develop a diabetic foot ulcer (DFU) in their lifetime, which can eventually result in amputation of the affected lower extremity[2,3]. DFU's are therefore considered a major concern in healthcare both from an economic and a quality of life perspective[2,4].

Neuropathy as a result of diabetes is considered to be the largest risk factor for DFU development, resulting in 90% of all DFU[5–8]. While peripheral vascular disease does not often result in pure ischaemic DFU, it does contribute to the ulceration in approximately 49% of all neuropathic DFUs[8,9]. Sensory neuropathy results in insensitivity causing a loss of proprioceptive and protective feedback that lead to trauma remaining unnoticed and problems with balance while standing and stability during walking. Limited joint motion and changes in foot structures as a result of diabetes lead to an increase of peak pressures (PP). The repetitive stresses at the location of the increased PP cause callus formation and/or small wounds that remain unnoticed because of the neuropathy, resulting in a DFU[8]. DFU typically develop at the metatarsal heads (MTHs) and the first toe, as PP is commonly increased at these areas[10–12]. Therefore, these areas are considered to be at high risk of ulcerations. The pathway to DFU is shown in figure 1.1.

For the prevention of DFU proper footcare and pressure reducing footwear is essential[7,8]. Also, patients at risk of developing DFU should never walk barefooted[7,8]. While dry skin can easily be noticed and larger problems can be prevented using moisturizing cremes[8,13–15], elevated pressures commonly remain unnoticed as a result of neuropathy[7,8,14]. Therefore, it is recommended to reduce PP to below 200 kPa[16] or, when this is not possible, by at least 30%[7] in patients that are considered at risk of developing DFU. Plantar PP are a direct result of the ground reaction force (GRF) interacting with the plantar surface of the foot, as simply put, pressure equals force divided by the contact area. Thus, to reduce PP at a certain area one can either reduce the force that is applied to the surface (or shift it to an area where it does no harm) or increase the contact area between the plantar surface of the foot

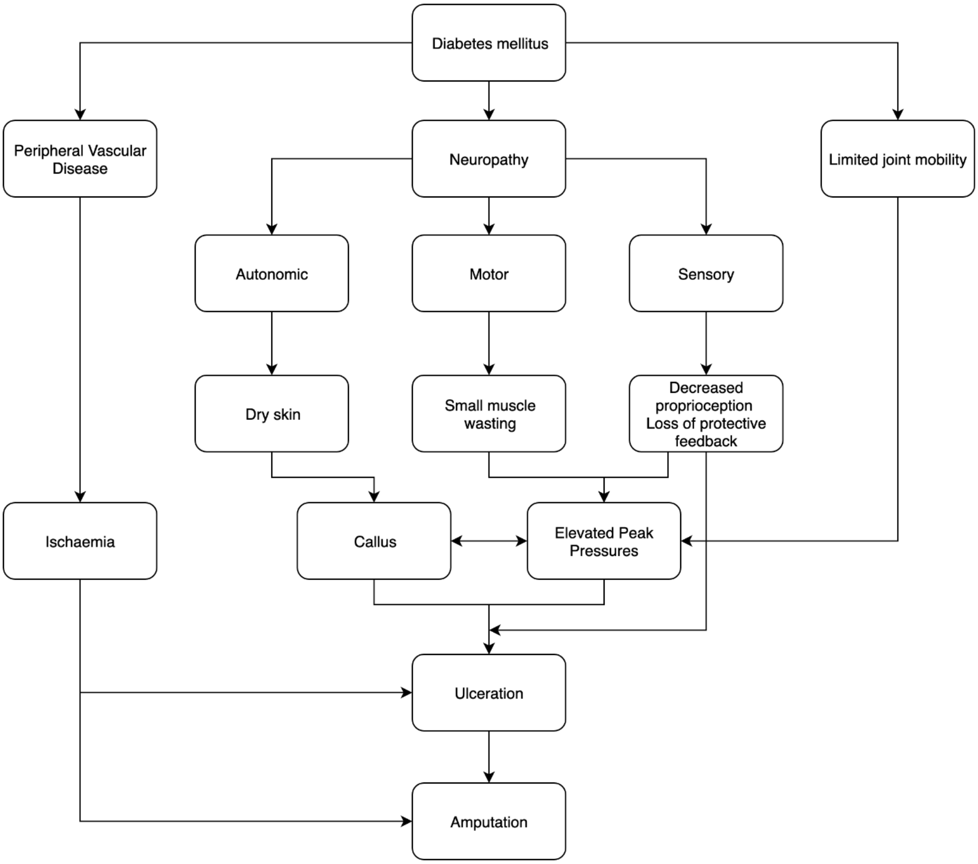

Figure 1.1: *Pathways to diabetic foot ulcerations*[8].

and the footwear. Rocker profiles and custom-made insoles use these methods of pressure redistribution to reduce PP.

Rocker profiles

Rocker profiles are commonly used to offload areas at risk by redirecting the point of application of the GRF away from the areas that are considered to be at risk of ulcerations. This is achieved by changing the orientation and position of the rocker axis (see figure 1.2), which is also referred to as the apex. The name rocker profile is based on the concept behind its mechanics which is rocking the foot from heel-strike to toe-off while restricting motion of the joints in the foot by stiffening the rocker profile[17,18]. Rollover is initiated when the point of application of the GRF passes the apex which allows for walking. There is literature that suggests that limiting joint motion at the metatarsophalangeal joints is needed to reduce PP at the

MTHs[17-20]. Therefore, rocker profiles are commonly stiffened in such a way that it is completely rigid and thus does not allow any plantar or dorsiflexion of the toes. However, the actual difference in offloading effects between rigid and flexible rocker profiles that allow dorsiflexion of the toes are not evaluated yet.

There are several design parameters (figure 1.2) that determine the rocker profile shape[19,20]. Changing these parameters results in offloading of different areas of the foot. The first design parameter is the apex position. This is the point where the apex intersects with the longitudinal axis of the shoe and is represented in percentage of the total shoe length measured along the longitudinal axis of the shoe [17,19,20]. For offloading of the MTHs an apex position between 50% and 60% is recommended, while an apex position of 65% seems to result in the best offloading of the first toe[19,20]. The second design parameter is the apex angle. This is the angle between the longitudinal axis of the shoe and the apex [19]. Rotating the medial side of the apex in a distal direction results in a decrease in apex angle. Apex angles between 90˚ and 100˚ result in offloading of MTH 1 and the first toe. Smaller apex angles, between 70˚ and 80˚, are beneficial for offloading of MTH 5.[19,20] Finally, the third design parameter describes the rocker curvature and is either called rocker angle or rocker radius. The rocker angle is the angle between the floor and the rocker profile distally from the apex. The rocker radius is the radius of the rocker profile. A rocker angle larger than 20˚ is recommended for offloading of the forefoot[19]. It should be noted that the beforementioned values for the apex position, apex angle, and rocker angle are average values. However, both studies described a large variability between subjects, which implies that these settings may not result in the best offloading for each individual.

While previous studies have described and quantified rocker profile design parameters they are not commonly described in daily practice, where the design of the rocker remains based on empirical knowledge and experience of the orthopaedic shoe technician and Rehabilitation or prescribing specialist.

Custom-made insoles

Custom-made insoles mostly reduce PP by increasing the contact surface between footwear and plantar surface of the foot. To do so, the shape of the insole is based on the shape of the patient’s foot and the insole is

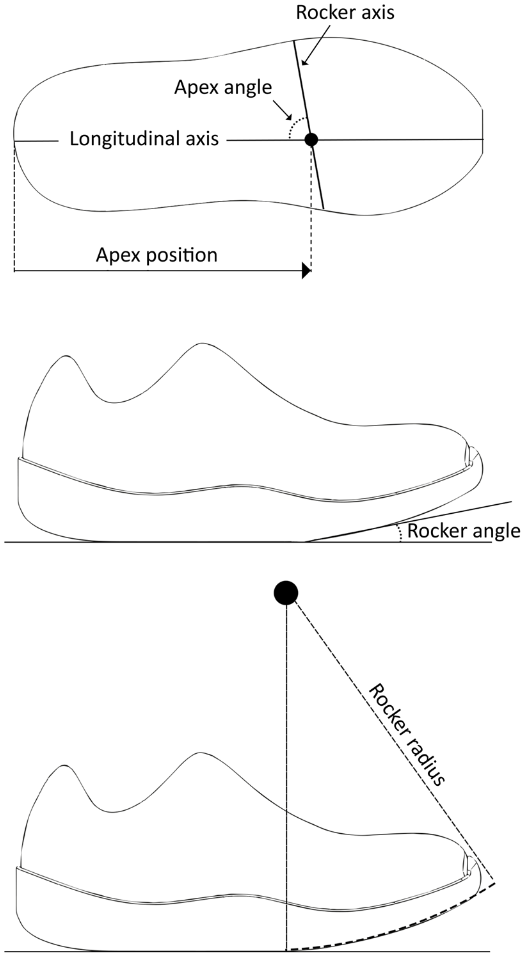

__Figure 1.2:__ Design parameters for rocker profiles. Top: Rocker axis (or apex), apex position and apex angle. Middle: Rocker angle. Bottom: Rocker radius.

constructed out of materials with different hardness values. Harder materials are commonly used for the supporting base of the insole, while softer materials are used to cushion at the locations of bony prominences. Also, insole material is commonly removed at the location of pressure spots to allow for redistribution of pressure to surrounding areas. The location of high pressure spots can be identified using blue prints of the foot[3]. A better way to determine the location of these pressure spots is by using in-shoe pressure measurement systems[7,20,21]. However, this is not possible at all orthopaedic footwear facilities as these measurement systems remain expensive.

Problems with current designs

In daily practice, both rocker profile and insole designs are based on empirical knowledge of orthopaedic shoe technicians and Rehabilitation specialists as guidelines are not well standardised[22]. As mentioned before, there is not a general design that results in the needed offloading for every individual. Therefore, the design of these shoe provisions is based on trial and error, which ideally requires making the footwear based on pressure measurements, measuring again to see if the needed pressure reduction is achieved, if not make adjustments until it meets the criteria of reducing PP to below 200 kPa[16] or by at least 30%[7]. This is a costly and time-consuming process. Also, due to changes in foot structures the location of PP can change over time in such a way that the footwear no longer results in offloading of the areas at risk, putting the patient at risk again of developing a DFU. Finally, both rocker profile and/or custom-made insole can negatively affect stability which may lead to falling and related trauma. Rocker profiles that are used with the intention of reducing PP commonly have the apex located proximal to the MTHs[19]. This results in a smaller base of support, which is known to reduce balance[23–25]. For insoles literature suggests that both materials and shape of the insole can negatively influence balance and stability[26–28].

The aim of this thesis is to design and evaluate innovative adjustable footwear to overcome the problems mentioned before that occur with footwear that is currently prescribed to prevent DFU.

Design

In order to get promising concepts that can be further developed into working prototypes, first a good understanding of the problem is needed. Chapter 2 describes this phase of the design process, which is called the *Analysis phase*. This analysis contains a more extensive problem definition and the goals that were aimed to be achieved. Also, a clear demarcation, design strategies, requirements and wishes, and function analyses that are needed to achieve these goals are described here.[29]

To get a better understanding on the functioning of shoes with rocker profiles literature was consulted on how different design parameters that determine the shape of the rocker profile affect PP at the plantar surface of the foot. It was commonly stated that rocker profiles need to be stiffened for optimal offloading[17,19,20], however there was no literature that studied the effects of rigid or flexible rockers on PP. Chapter 3 describes these effects, as a contribution to the design process.

Evaluation

Chapter 4 introduces the first innovative concept, the adjustable rocker profile prototype. With the adjustable rocker profile it is possible to repeatedly adapt the rocker shape within seconds using only a screwdriver in contrary to adjusting the shape of a fixed rocker profile, which needs special machinery and takes a lot of time. This gives the possibility for easy personalized optimization of the rocker profile, based on pressure measurements, and it allows for the changes in the rocker shape that are needed when the location of pressure spots change over time. In this chapter the effects of seven rocker settings and a control on plantar PP are examined in healthy male participants.

The second innovative concept, the self-adjusting insole, is introduced in Chapter 5. The self-adjusting insole is a flat insole that consists entirely of small elements that collapse only when plantar pressures exceed a certain threshold, resulting in a lowering of the supporting surface at that specific location and thus a lowering of the pressure. This mechanism allows for offloading at the locations where pressures are too high by redistribution of pressure across the neighbouring elements that did not collapse. Functionality of this prototype is examined both mechanically and in healthy participants during walking.

In Chapter 6 the effects of the combination of both the adjustable rocker profile and self-adjusting insole on in-shoe pressures are evaluated in healthy participants, as combining rocker profiles and insole can contribute to offloading of dangerous PP[21,30].

While much insight can be gained by studying the effects of the newly developed adjustable rocker profile and self-adjusting insole in healthy participants it is always necessary to see how these effects translate to the target group, in this case people with diabetes mellitus that have developed peripheral neuropathy. Chapter 7 describes the effects of both the adjustable rocker profile and self-adjusting insole, separately and combined on PP in people with diabetes and neuropathy.

Finally, the outcomes of this thesis are discussed in Chapter 8. In this chapter the two innovative concepts will be judged based on findings from the previous chapters. Also, clinical implications, limitations, and future research will be addressed.

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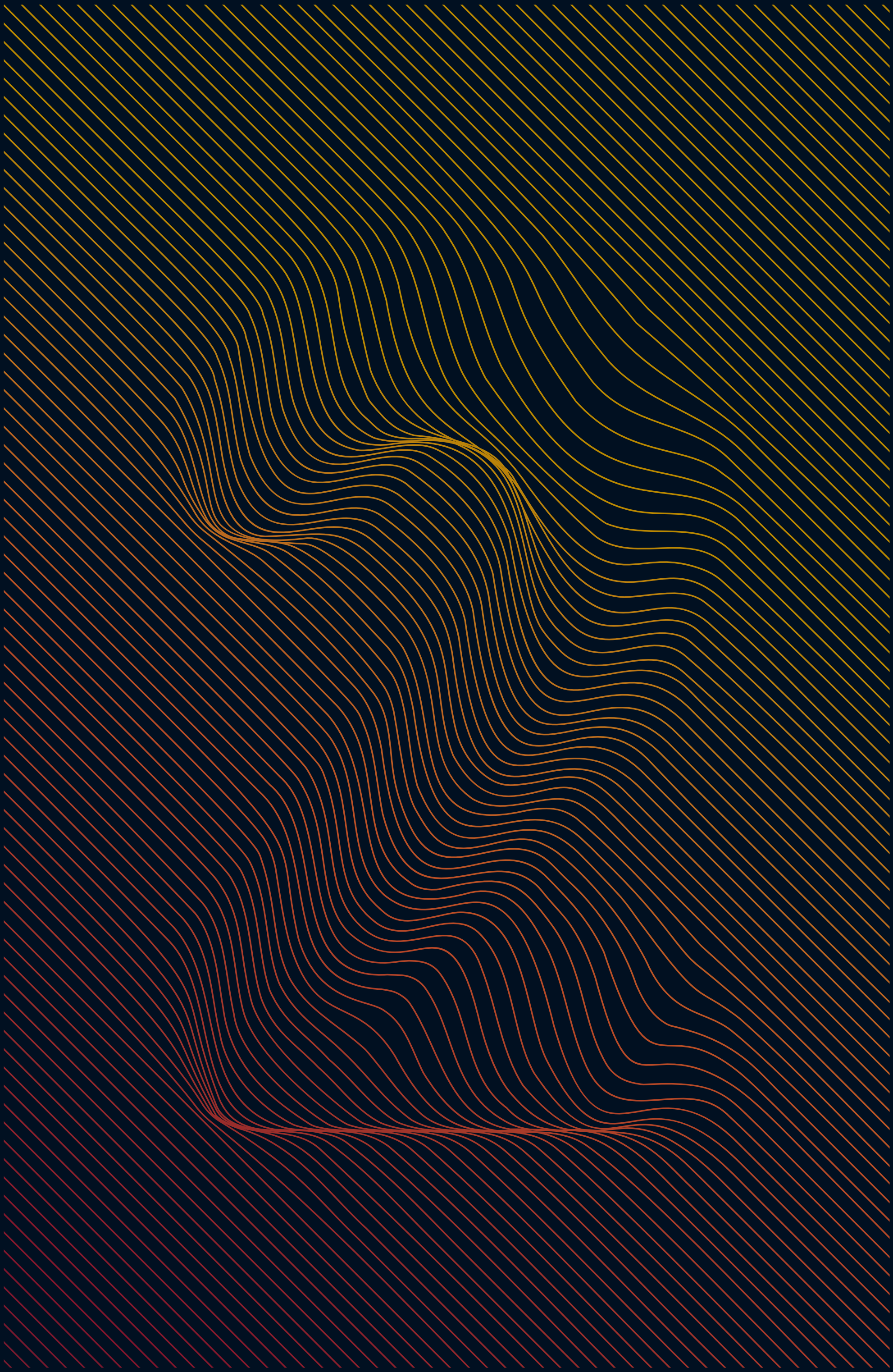


ANALYSIS

Problem definition

As described in chapter 1, diabetic foot ulcers (DFUs) disrupt the life of millions of people. Rocker profiles and custom-made insoles are commonly prescribed to reduce peak pressures (PP) in order to prevent DFUs. However, the design of both is based mainly on experience which can result in insufficient initial offloading. When initial offloading is sufficient, the location of dangerous PP can shift over time as a result of changes in foot structures, putting the patient at risk of DFU development again. Figure 2.1 shows the cause and effects of often occurring problems with currently used preventive footwear.

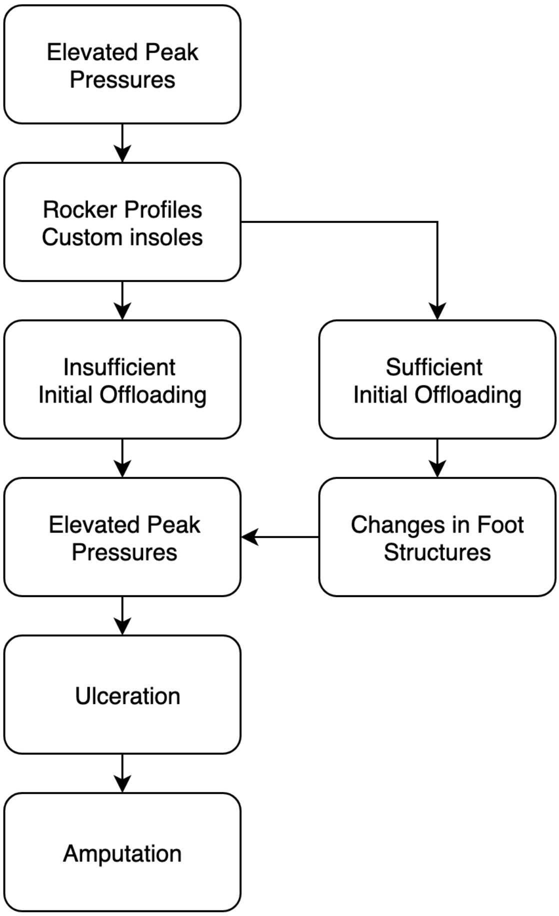


Figure 2.1: *Cause and effect diagram of often occurring problems with the use of current preventive footwear.*

Goals

The main goal of this dissertation is to develop adjustable footwear that ensures offloading of PP that are considered too high, and can accommodate when the location of these PP change over time. By doing so, the chance of DFU development and with that amputation decreases. The cause and effect diagram that shows the effects of the adjustable devices is represented in figure 2.2.

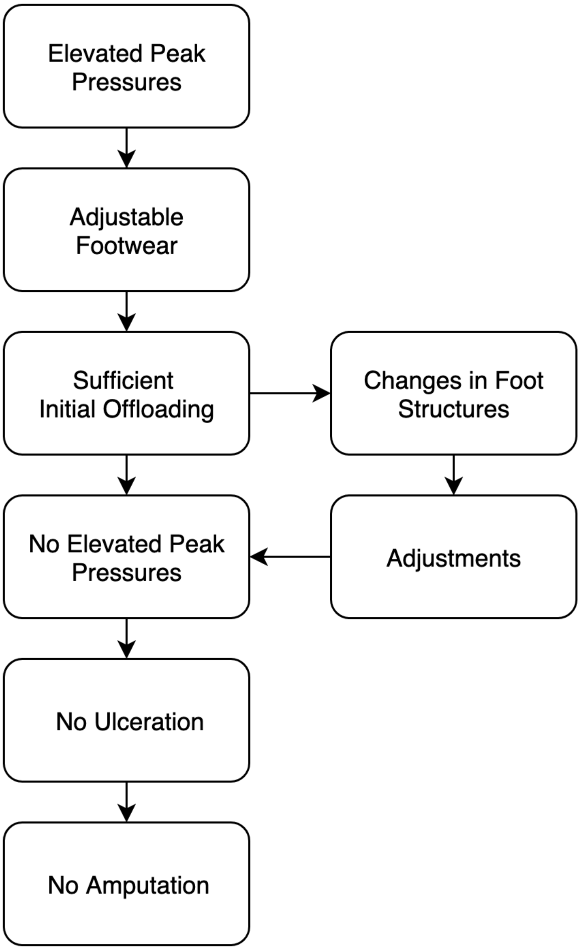


Figure 2.2: *Goals of the devices to be developed.*

Design assignment

The design assignment for this dissertation consists of realising working prototypes of the adjustable footwear mentioned above. The intended users consists of adults with diabetes that have developed neuropathy, as these users represent the group that is considered to be at risk of developing DFU. During the design process two design assignments are used. The first assignment is the development of an adjustable rocker profile of which the orientation and location of the apex can easily be changed without the need of an orthopaedic workshop. The second assignment is the design of an insole that automatically adjusts to PP that are considered too high. The targeted areas for offloading are the forefoot and first toe as most plantar pressure related DFU occur these areas. Dr Comfort (Mequon, WI, USA) shoes will be used for the design of the prototypes.

Requirements

Both the adjustable rocker profile and the self-adjusting insole have to fulfil several requirements to be successful. These requirements are described for both devices separately.

Adjustable rocker profile

The requirements for the adjustable rocker profile are listed in table 2.1.

Table 2.1: *The requirements for the adjustable rocker profile.*

ID	Requirement
R-1. Functional	*The adjustable rocker profile must;*
R-1.1	Reduce PP to below 200 kPa or by 30%
R-1.2	Allow for rocker axis adjustability
R-1.2.1	Apex position: 50% - 65% of the total shoe length
R-1.2.2	Apex angle: 70˚ – 100˚
R-1.2.3	Without the need of an orthopaedic workshop
R-1.2.4	Within 5 minutes
R-1.3	Be suitable for users that weigh less than 135 kg
R-1.4	Be suitable for users with shoesizes 36-46EU
R-1.5	Be suitable for users that fit in conventional shoes
R-1.6	Be able to be used 7 days a week
R-1.7	Have a lifespan of more than 1 year
R-1.7.1	Repeatability > 3000000 steps
R-2. Size	*The adjustable rocker profile must;*
R-2.1	Fit the outline of the used shoe
R-2.2	Not increase the shoe height by more than 25 mm
R-2.3	Weigh less than 1000 grams per pair
R-3. Safety	*The adjustable rocker profile must;*
R-3.1	Not decrease the stability during gait compared to non-adjustable rocker profiles
R-3.2	Not adjust during walking
R-4. Ergonomical	*The adjustable rocker profile must;*
R-4.1	Be perceived as comfortable
R-5. Aesthetical	*The adjustable rocker profile must;*
R-5.1	Not be less attractive to wear compared to current ulcer preventive footwear
R-6. Cost	*The adjustable rocker profile must;*
R-6.1	Cost less than 100 euro for manufacturing per pair (excluding shoes)

Self-adjusting insole

The requirements for the self-adjustable insole are listed in table 2.2.

Table 2.2: *The requirements for the adjustable rocker profile.*

ID	Requirement
I-1. Functional	*The self-adjusting insole profile must;*
I-1.1	Reduce PP to below 200 kPa or by 30%
I-1.2	Adjust automatically to pressures of 200 kPa or larger
I-1.2.1	At the areas at risk (MTH1-5 and first toe)
I-1.2.2	Lowering insole surface only locally (area below 1.50 cm^2)
I-1.2.3	Have a maximum vertical displacement of 5 mm when adjusting to pressures
I-1.3	Be suitable for users that weigh less than 135 kg
I-1.4	Be suitable for users with shoesizes 36-46EU
I-1.5	Be suitable for users that fit in conventional shoes
I-1.6	Be able to be used 7 days a week
I-1.7	Have a lifespan of more than 1 year
I-1.7.1	Repeatability > 3000000 steps
I-2. Size	*The self-adjusting insole profile must;*
I-2.1	Have a maximal thickness of 9 mm
I-2.2	Fit inside the used Dr Comfort shoe
I-2.3	Weigh less than 200 grams per pair
I-3. Safety	*The self-adjusting insole profile must;*
I-3.1	Not decrease the stability during gait compared to walking without an insole
I-3.2	In case of electronics have;
I-3.2.1	Enclosure leakage current of less than 300 µA
I-3.2.2	Patient leakage current of less than 10 µA
I-4. Ergonomical	*The self-adjusting insole profile must;*
I-4.1	Be perceived as comfortable
I-5. Cost	*The self-adjusting insole profile must;*
I-5.1	Cost less than 70 euro for manufacturing per pair

Function analysis

Function analyses are used to describe the internal functions of the devices that are to be designed. The general function analysis for both the adjustable rocker profile and the self-adjusting insole is shown in figure 2.3.

While this function analysis provides general insight in what both devices should do, there are great differences in how they need to function exactly. Therefore, more in depth schematics for both concepts separately are presented below.

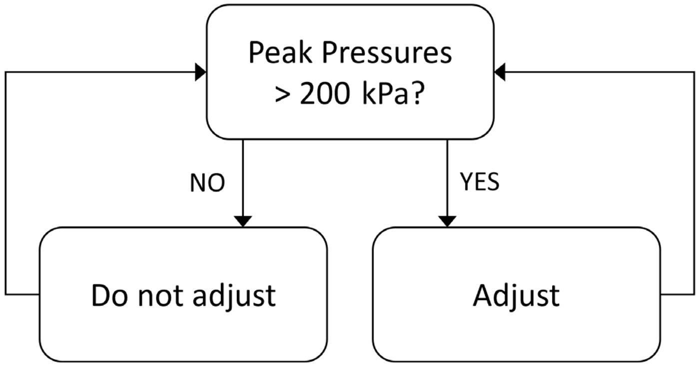


Figure 2.3: *General function analysis for both devices.*

Adjustable Rocker profile

Plantar pressures should be measured using a sensory system like the commonly used Pedar-X system (Novel Gmbh, Munich, Germany), and is not part of the adjustable rocker design. When PP are over 200 kPa the adjustable rocker profile should allow for manual changes in the orientation and position of the apex. This first requires loosening of the apex, after which the apex angle and/or position can be altered. Finally, the apex needs to be secured in place so it does not move during use. The function analysis for the adjustable rocker profile is shown in figure 2.4.

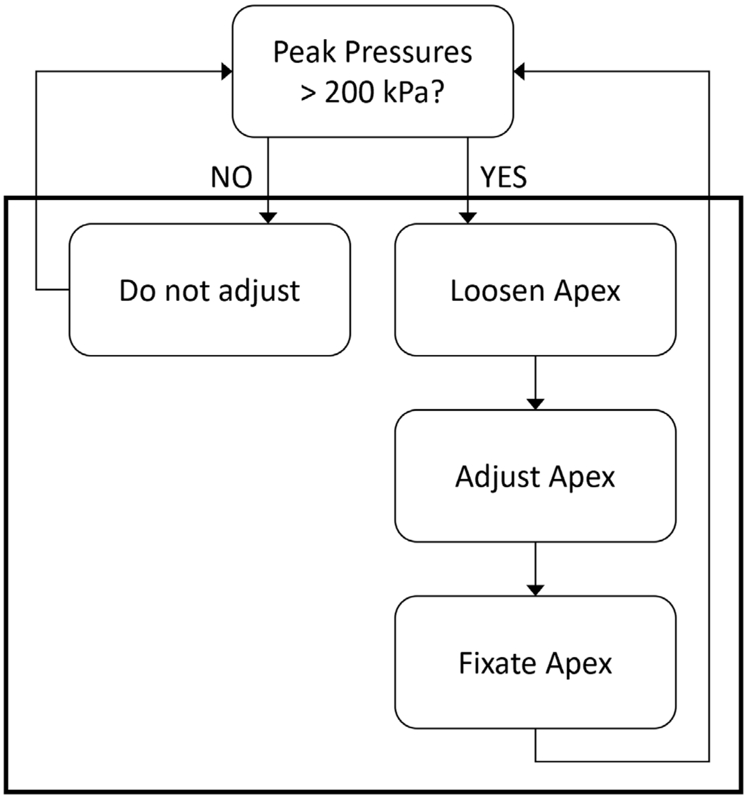


Figure 2.4: *Function analysis for the adjustable rocker profile. The demarcation of the functions that are part of the adjustable rocker profile design is shown with a solid black line.*

Self-adjusting insole

The self-adjusting insole should automatically adjust to PP over 200 kPa. These adjustments result in lowering of the insole surface and should only occur at the location of the high PP Also, the insole surface should return to its original shape during the swing phase of gait. The threshold of 200 kPa could be established either mechanically or with a sensory system, and is part of the self-adjusting insole design. The function analysis for the self-adjusting insole is shown in figure 2.5.

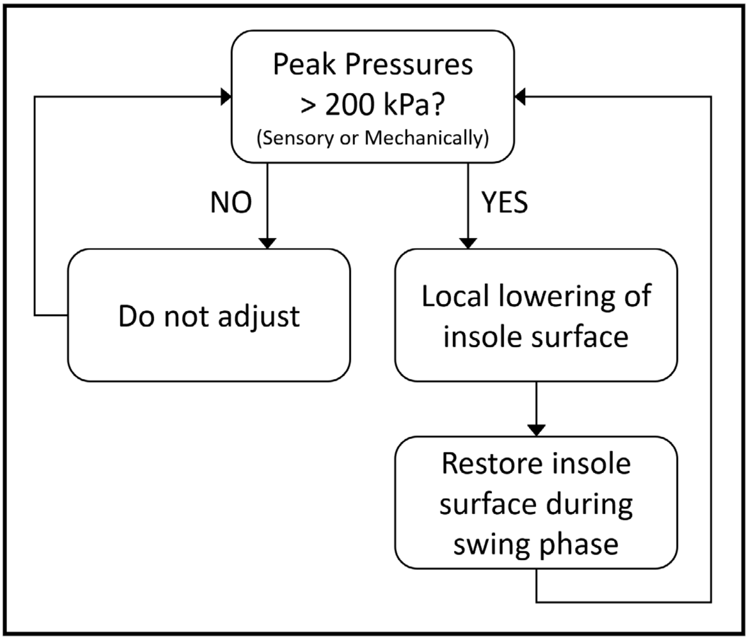
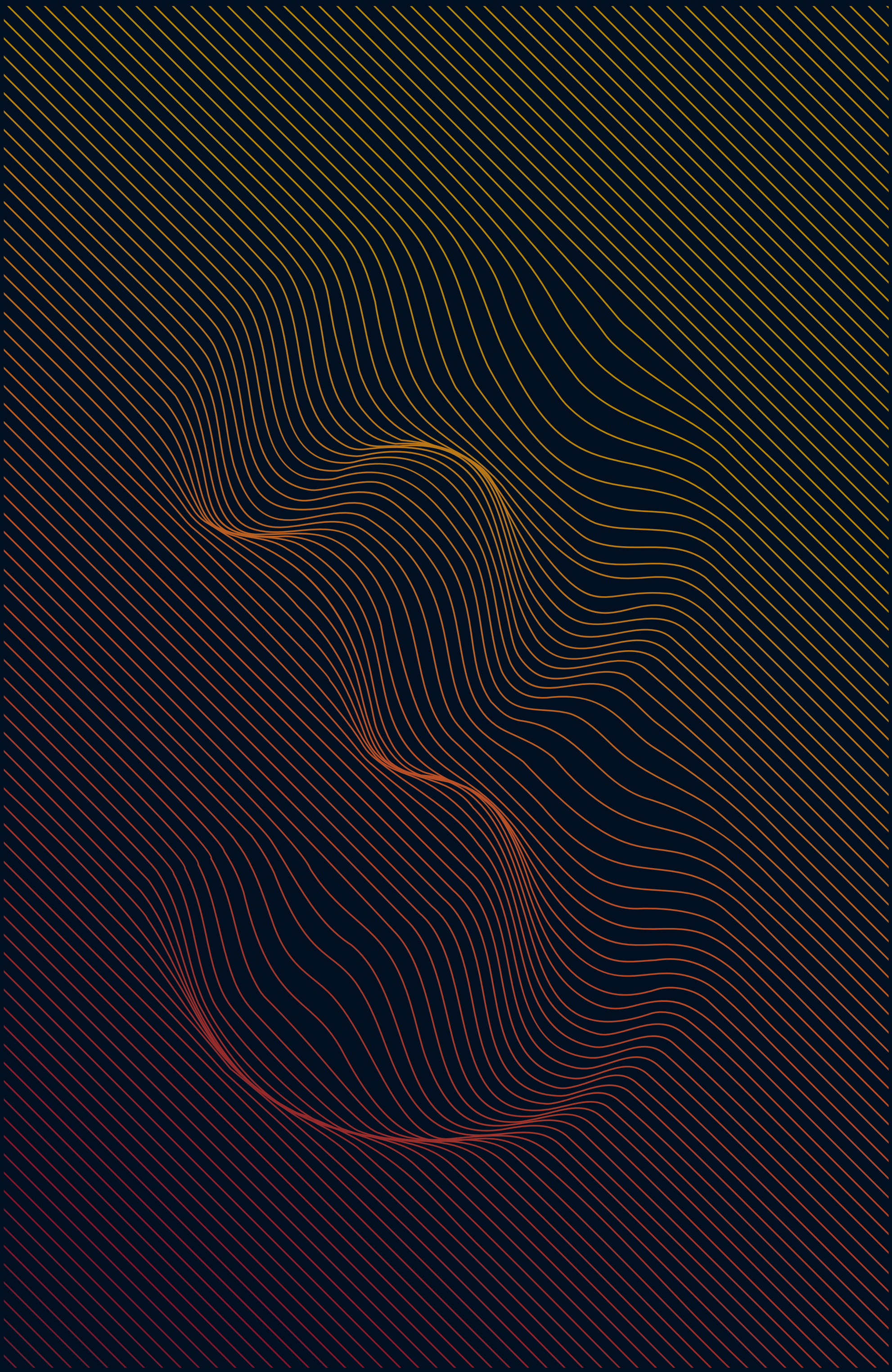


Figure 2.5: *Function analysis for the self-adjusting insole. The demarcation of the self-adjusting insole are represented with a solid black line.*



EFFECTS OF FLEXIBLE AND RIGID ROCKER PROFILES ON IN-SHOE PRESSURE

Abstract

Rocker profiles are commonly used in the prevention of diabetic foot ulcers. Rockers are mostly stiffened to restrict toe plantarflexion to ensure proper offloading. It is also described that toe dorsiflexion should be restricted. However, the difference in effect on plantar pressure between rigid rockers that restrict this motion and flexible rockers that do not is unknown. In-shoe plantar pressure data were collected for a control shoe and the same shoe with rigid and flexible rockers with the apex positioned at 50% and 60%. For 29 healthy female adults peak plantar pressure (PP), maximum mean pressure (MMP) and force-time integral (FTI) were determined for seven regions of the foot. Generalized estimate equation was used to analyse the effect of the different shoes on the outcome measures for these regions. Compared to the control shoe a significant increase of PP and FTI was found at the first toe for both rigid rockers and the flexible rocker with the apex positioned at 60%, while MMP was significantly increased in rockers with an apex position of 60% ($p<0.001$). PP at the first toe was significantly lower in flexible rockers when compared to rigid rockers ($p<0.001$). For both central and lateral forefoot PP and MMP were significantly more reduced in rigid rockers ($p<0.001$), while for the medial forefoot no differences were found. The use of rigid rockers results in larger reductions of forefoot plantar pressures, but in worse increase of plantar pressures at the first toe compared to rockers that allow toe dorsiflexion.

R. Reints, J.M. Hijmans, J.G.M. Burgerhof, K. Postema, G.J. Verkerke

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Introduction

Up to 25% of all patients with Diabetes Mellitus (DM) will develop foot ulcers, which may eventually lead to amputation of the affected foot[1,3]. Most ulcers develop at the forefoot and first toe mainly due to changes in foot structures leading to elevated pressures at these sites[4-6]. Especially patients who have developed peripheral neuropathy as a result of DM are at high risk, because of reduced protective sensation[2,5].

Rocker profiles can be used to prevent development of diabetic foot ulcers by reducing pressure at the forefoot, where the metatarsal heads (MTH) are located, and the plantar tip of the first toe[7,8]. When designing a rocker profile, there are several features that can be altered to achieve the preferred offloading. The apex position, indicating the start of the rocker on the longitudinal axis of the shoe, is one of these variables. Previous studies have shown that offloading of the forefoot was achieved by an apex position placed between 50-60% of the longitudinal axis, measured from the heel[9,12]. Another variable that can be altered is the apex angle, which indicates the angle between the apex and the longitudinal axis of the shoe. The apex angle is at 90° when placed perpendicular to the longitudinal and can be increased or decreased when the most lateral point of the apex is rotated in distal or proximal direction respectively[13].

Rocker profiles are mostly stiffened to limit sagittal plane motion of the Metatarsal phalangeal joints[10,13]. Flexibility that allows plantar flexion of the toes is never desired as it will compromise the rollover shape of the rocker profile, which can cause an increase in plantar pressure at the apex region. In literature it is sometimes stated that also dorsiflexion of the toes should be restricted to ensure that the ground reaction force is distributed over a larger area[10]. However, to the best of our knowledge, there have not been any studies that evaluated the difference in effect on plantar pressure between completely rigid rockers and flexible rocker profiles that only allow dorsiflexion of the toes. Therefore, the aim of the current study was to evaluate this difference in effect.

We hypothesize that the use of completely rigid rocker profiles will result in larger pressure reductions at the forefoot and first toe compared to rocker profiles that allow dorsiflexion of the toes. The hypothesis will be tested in rocker profiles with the apex positioned at 50% and 60% as these positions have shown to result in the best pressure reduction for the forefoot when walking on rigid rockers[10,11], while the apex angle remains similar to the control shoe. For the apex position we expect larger plantar pressure reduction at the forefoot compared to the control shoe when the apex positioned at 60% when compared to 50%[10,11].

Methods

Participants

Thirty healthy female adults participated in this study. Inclusion criteria were female sex, age 18 years and older, and shoe sizes EU38/39/40. This subgroup was selected to minimize the amount of shoes to be modified. Exclusion criteria were the use of custom inlays and self-reported pathologies or injuries that influence gait. All participants provided written informed consent before starting the experiments. The local Medical Ethics Committee approved conduct of this study (METc 2016.087).

Shoe conditions

Double depth shoes (Refresh-X, Dr Comfort, Mequon, WI, USA) sizes EU 38M, 39M and 40M were used in this study. This type of shoes is commonly used in people with DM. For each size two pairs were modified, and one unmodified pair was used as control (figure 3.1a-3.1c). The original soles of the modified pairs were sanded off and 20mm of Ethylene-vinyl acetate (EVA, 63 durometers, shore A) was used as replacement. The apex of the modified pairs was positioned at 50% and 60% of the total shoe length. For both modified pairs the apex angle (85°) and the radius (190mm) were kept similar to the control shoe. Two cuts completely through the added EVA were made parallel to the apex at 55% and 70%, only allowing flexibility of the shoes for toe dorsiflexion (figure 3.1d-3.1e). The position of these cuts corresponded to the notches that facilitate flexibility in the original sole design, and ensured that toe dorsiflexion is allowed for each participant as MTH1 is located between the cuts[10]. The force needed to dorsiflex the modified pairs was similar to the unmodified pair.

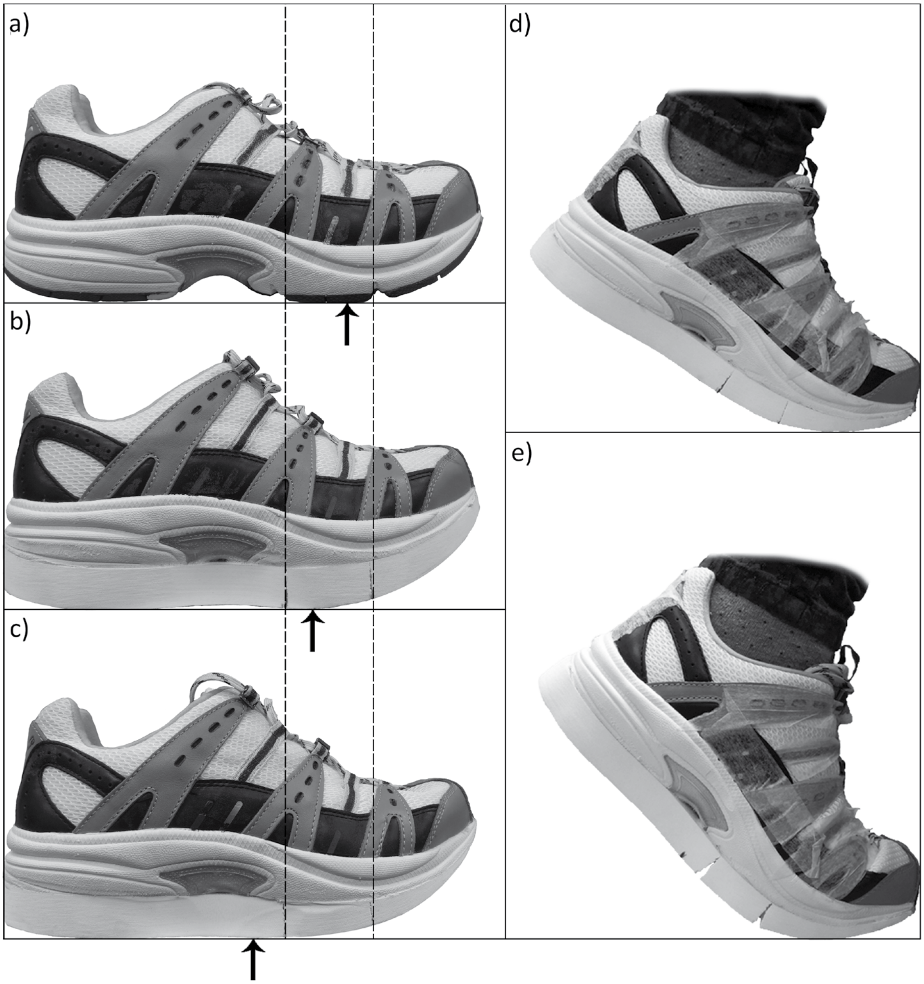

Figure 3.1: *Shoe modifications. On the left the apex positions for the control (a), modified shoe with apex position at 60% (b) and modified shoe with apex position at 50% (c) are indicated with a black arrow. The dashed lines indicate the position of the notches in the original sole and the cuts in the modified shoes. On the right the difference between the rigid (d) and flexible (e) configurations is shown (both loaded).*

The modified shoes allowed for a total of four experimental configurations; 1) flexible with apex position at 50% (Flex50), 2) rigid with apex position at 50% (Rigid50), 3) flexible with apex position at 60% (Flex60), and 4) rigid with apex position at 60% (Rigid60). For rigid configurations the shoes were stiffened with removable carbon inserts. For flexible configurations and control shoes a cardboard insert of the same thickness was used. Flat EVA inlays (25 durometers, shore A, thickness: 6mm) that came with the shoes were placed on top of the inserts for comfort. The mean(±SD) weight for each pair of shoes was 667(±33), 686(±20), 749(±19), 728(±37), and 790(±41) grams for Control, Flex50, Rigid 50, Flex60, and Rigid60 respectively.

In-shoe pressure measurements

Pedar-X® insoles (Novel; Munich, Germany) were used to measure In-shoe plantar pressure. The insoles were calibrated by the manufacturer. The sampling frequency was set to 100Hz and data were collected from both feet.

Experimental procedures

All measurements were performed at the Motion Lab of the Department of Rehabilitation Medicine, University Medical Center Groningen. Height and bodyweight were recorded and each participant was asked what foot she uses to kick a ball to determine the dominant foot. All participants were given the same type of socks (Ankle socks, Dr Comfort, Mequon, WI, USA). The control shoe was the first condition to determine the preferred walking speed. The following experimental conditions were first randomized on apex position (50% or 60%) after which flexible and rigid configurations were randomly assigned for each apex position. For each condition the Pedar-X® insoles were placed on top of the EVA inlays and zeroed as recommended by the manufacturer. For each condition three trials of walking up and down the aisle of the Motion lab were recorded. Preferred walking speed was determined using the SpeedClock application (Sten Kaiser, v9.1). Following trials in which the walking speed differed more than 10% from the preferred walking speed were deleted and repeated. Each participant scored shoe comfort after the last trial of each condition by placing a vertical line on a 100mm Visual Analog Scale (VAS). The outmost left (0mm) was labelled very uncomfortable and the outmost right (100mm) was labelled very comfortable.

Data analysis

Only data from the dominant leg were analysed. For each trial the middle two steps for both walking up and down the aisle were selected using Pedar-X® Step analysis (Novel; Munich, Germany), resulting in twelve steps per condition for each participant[14]. Using Matlab (R2013a) data were further analysed. The sensors of the Pedar-X® insole were divided into seven masks (figure 3.2) representing: 1) first toe, 2) other toes, 3) medial forefoot, 4) central forefoot, 5) lateral forefoot, 6) midfoot and 7) heel[15]. Masks 1, 3, and 4 represent areas of the foot that are at largest risk for ulcerations[16]. Chapman et al.(2013) showed that changing apex positions and apex angles influences the pressure distribution across these masks[11]. Peak pressures (PP), maximal mean pressures (MMP) and force time integral (FTI) were calculated for each mask. PP was determined by selecting the peak pressures within each mask for every step. To determine MMP first the mean pressure for each mask was calculated for all timeframes within a single step, after which the timeframe with the maximum mean pressure was selected for every step. Finally, to determine FTI first forces were calculated for each sensor by multiplying all recorded pressures within a step with its own sensor area. Then FTI was determined as the sum of forces for each step divided by the frequency within each mask. VAS-scores were determined by measuring the distance from the left side of the scale up to the line drawn by the participant.

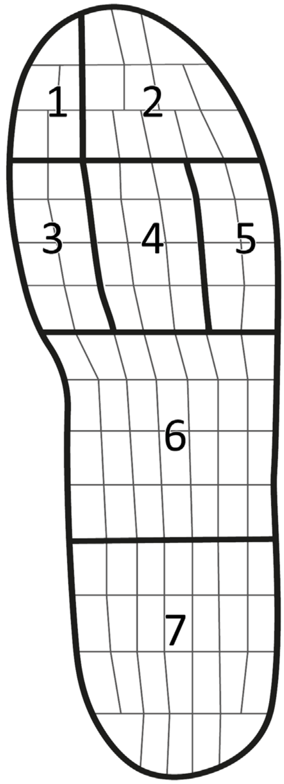

Figure 3.2: *Division of the 99 sensors of one Pedar® insole into seven masks. The numbers represent the following masks, 1: first toe, 2: other toes, 3: medial forefoot, 4: central forefoot. 5: lateral forefoot, 6: midfoot, and 7: heel.*

Statistical analysis

Means and standard deviations were determined to describe study population characteristics. PP, MMP and FTI were analysed separately using generalized estimate equation (GEE) with shoe condition, mask and step as within subject variables estimating the response of the shoe conditions. Natural log transformation was used for FTI as there was a positive skew the distribution. Friedman's test was used to analyse VAS for all shoe conditions. Post hoc Wilcoxon signed rank testing was used for pairwise comparison. All statistical analyses were performed using SPSS statistics (23.0.0.0). For both overall tests the level of significance was set at $p<0.05$. For pairwise comparison using GEE and Wilcoxon signed rank testing Bonferroni correction was applied, resulting in a level of significance set at $p<0.001$ and $p<0.005$ respectively.

Results

Data for one participant were removed from the study, as it was not possible to select the needed steps with Pedar-X® Step analysis. For four of the remaining 29 participants one of the selected steps was removed because of missing data at the beginning or end of these steps. The analysed participants had a mean(±SD) age of 22(±2) years, bodyweight of 65.5(±8.4) kg, and body height of 1.73(±0.06) m. The average walking speed was 1.43(±0.19) m/s.

Means and 95% confidence intervals for PP, MMP and FTI can be found in table 3.1. The overall GEE, showed a significant difference between shoe conditions in PP ($p=0.032$), MMP ($p<0.001$) and FTI ($p<0.001$). Differences in PP, MMP and FTI are visualized in figure 3.3.

Below only relevant statistically significant changes between rigid and flexible rockers (compared to the control) are described. Absolute values can be found in table 3.1 and relative changes are represented in figure 3.3. Compared to the control PP was significantly increased in all rockers, except Flex50. The increase in PP was significantly larger ($p<0.001$) in rigid rockers compared to flexible rockers.

Table 3.1: *Absolute values for in-shoe outcome parameters and p-values for corresponding pairwise comparisons. Flex 50: Flexible rocker with apex positioned at 50%. Rigid 50: Rigid rocker with apex positioned at 50%. Flex 60: Flexible rocker with apex positioned at 60%. Rigid 60: Rigid rocker with apex positioned at 60%. CI: Confidence interval. P1: p- value found for comparison between control and Flex 50. P2: p-value found for comparison between control and Rigid 50. P3: p-value found for comparison between control and Flex 60. P4: p-value found for comparison between control and Rigid 60. P5: p-value found for comparison between Flex 50 and Rigid 50. P6: p-value found for comparison between Flex 60 and Rigid 60. P7: p-value found for comparison between Flex 50 and Flex 60. P8: p-value found for comparison between Rigid 50 and Rigid 60. PP: Peak Plantar Pressure. MMP: Maximum Mean Pressure. FTI: Force-time integral. FF: Forefoot.*

	Control	Flex 50	Rigid 50	Flex 60	Rigid 60	p-values							
	mean [95% CI]	mean [95% CI]	mean [95% CI]	mean [95% CI]	mean [95% CI]	p_1	p_2	p_3	p_4	p_5	p_6	p_7	p_8
PP (kPa)													
First toe	215,0 [187,5 ; 242,5]	231,7 [201,9 ; 261,6]	258,2 [225,0 ; 291,3]	231,6 [204,6 ; 258,6]	256,9 [222,8 ; 291,1]	0,028	**<0.001**	**<0.001**	**<0.001**	**<0.001**	**<0.001**	0,981	0,875
Other toes	133,0 [118,8 ; 147,3]	126,8 [113,3 ; 140,2]	126,7 [111,5 ; 142,0]	123,2 [110,9 ; 135,6]	118,7 [107,4 ; 130,0]	0,234	0,369	0,019	0,001	0,994	0,160	0,360	0,108
Medial FF	158,7 [144,2 ; 173,2]	151,5 [138,3 ; 164,8]	151,6 [137,3 ; 166,0]	149,0 [137,5 ; 160,6]	158,2 [143,8 ; 172,6]	0,009	0,055	**<0.001**	0,881	0,972	0,008	0,226	0,014
Central FF	170,3 [160,2 ; 180,4]	154,5 [145,5 ; 163,4]	139,6 [130,5 ; 148,8]	159,3 [150,2 ; 168,4]	150,6 [141,0 ; 160,3]	**<0.001**	**<0.001**	**<0.001**	**<0.001**	**<0.001**	**<0.001**	0,049	**<0.001**
Lateral FF	137,8 [127,0 ; 148,6]	119,2 [110,3 ; 128,2]	107,6 [98,9 ; 116,2]	126,2 [115,3 ; 137,0]	114,7 [106,1 ; 123,2]	**<0.001**	**<0.001**	**<0.001**	**<0.001**	**<0.001**	**<0.001**	0,014	0,001
Midfoot	82,6 [73,4 ; 91,8]	86,1 [76,5 ; 95,7]	88,2 [77,6 ; 98,8]	79,9 [70,9 ; 88,9]	85,4 [75,8 ; 95,0]	0,150	0,038	0,173	0,288	0,278	0,018	0,049	0,287
Heel	215,0 [201,4 ; 228,7]	236,9 [224,6 ; 249,2]	247,0 [232,8 ; 261,2]	241,3 [229,0 ; 253,7]	252,0 [235,5 ; 268,5]	**<0.001**	**<0.001**	**<0.001**	**<0.001**	**<0.001**	**<0.001**	0,089	0,155
MMP (kPa)													
First toe	138,6 [123,0 ; 154,2]	146,0 [129,4 ; 162,7]	148,5 [130,9 ; 166,2]	151,0 [134,6 ; 167,4]	154,6 [137,4 ; 171,8]	0,073	0,063	**<0.001**	**0,000**	0,476	0,141	0,108	0,206
Other toes	70,3 [63,6 ; 77,0]	68,5 [62,1 ; 75,0]	61,5 [55,1 ; 67,9]	67,6 [60,7 ; 74,6]	60,0 [54,3 ; 65,7]	0,437	**<0.001**	0,137	**<0.001**	**<0.001**	**<0.001**	0,596	0,349
Medial FF	98,4 [87,6 ; 109,2]	98,0 [88,2 ; 107,8]	96,9 [86,4 ; 107,3]	101,0 [91,0 ; 111,0]	104,5 [93,9 ; 115,0]	0,884	0,587	0,333	0,011	0,536	0,089	0,135	**<0.001**
Central FF	108,4 [100,6 ; 116,2]	100,4 [95,0 ; 105,8]	90,1 [83,5 ; 96,8]	107,5 [100,9 ; 114,1]	101,9 [95,1 ; 108,8]	**<0.001**	**<0.001**	0,585	0,002	**<0.001**	**<0.001**	**<0.001**	**<0.001**
Lateral FF	90,9 [82,7 ; 99,0]	78,1 [71,0 ; 85,2]	72,3 [65,6 ; 79,1]	83,7 [75,9 ; 91,4]	76,7 [70,0 ; 83,3]	**<0.001**	**<0.001**	**<0.001**	**<0.001**	**<0.001**	**<0.001**	**<0.001**	**<0.001**
Midfoot	25,0 [21,2 ; 28,8]	31,6 [26,9 ; 36,4]	29,1 [24,5 ; 33,8]	24,1 [20,7 ; 27,5]	25,1 [21,6 ; 28,7]	**<0.001**	**<0.001**	0,356	0,848	**<0.001**	0,198	**<0.001**	**<0.001**
Heel	130,1 [121,2 ; 139,0]	141,0 [134,0 ; 147,9]	141,3 [133,6 ; 148,9]	140,8 [132,6 ; 149,0]	139,8 [130,8 ; 148,8]	**<0.001**	**<0.001**	**<0.001**	**<0.001**	0,783	0,356	0,902	0,382
FTI (N s)													
First toe	18,4 [15,8 ; 21,5]	20,6 [17,9 ; 23,6]	22,0 [19,0 ; 25,4]	21,8 [18,7 ; 25,5]	23,2 [20,0 ; 26,9]	0,006	**<0.001**	**<0.001**	**<0.001**	0,014	0,012	0,058	0,159
Other toes	23,3 [20,2 ; 27,0]	22,8 [20,3 ; 25,6]	20,9 [18,5 ; 23,8]	23,7 [20,6 ; 27,2]	21,7 [19,2 ; 24,5]	0,633	0,015	0,724	0,058	0,007	**<0.001**	0,363	0,331
Medial FF	27,3 [23,5 ; 31,7]	27,3 [23,8 ; 31,4]	28,8 [25,0 ; 33,1]	29,4 [25,4 ; 33,9]	30,7 [27,2 ; 34,7]	0,975	0,166	0,019	**<0.001**	0,036	0,128	0,016	0,045
Central FF	51,2 [47,1 ; 55,5]	45,3 [42,6 ; 48,2]	42,8 [39,5 ; 46,3]	51,9 [48,3 ; 55,8]	49,6 [45,9 ; 53,5]	**<0.001**	**<0.001**	0,489	0,173	0,002	0,009	**<0.001**	**<0.001**
Lateral FF	31,6 [28,2 ; 35,4]	27,2 [24,7 ; 29,9]	26,3 [23,8 ; 29,2]	30,2 [27,3 ; 33,5]	28,4 [25,9 ; 31,1]	**<0.001**	**<0.001**	0,133	**<0.001**	0,204	0,013	**<0.001**	0,012
Midfoot	26,0 [20,2 ; 33,4]	33,8 [26,0 ; 44,0]	31,1 [23,8 ; 40,7]	26,3 [20,8 ; 33,2]	29,2 [23,4 ; 36,3]	**<0.001**	**<0.001**	0,860	0,002	0,006	0,053	0,002	0,195
Heel	110,5 [100,4 ; 121,7]	137,7 [130,8 ; 144,8]	137,6 [129,4 ; 146,3]	132,2 [125,2 ; 139,7]	130,2 [122,6 ; 138,3]	**<0.001**	**<0.001**	**<0.001**	**<0.001**	0,976	0,226	**<0.001**	0,002

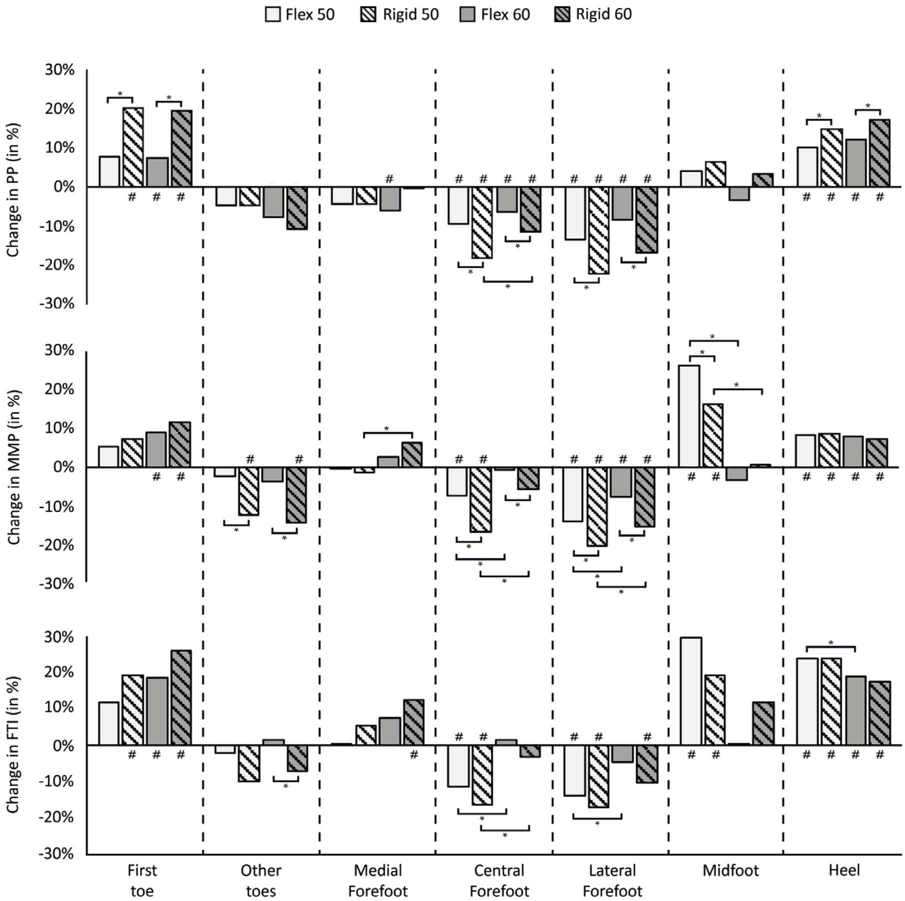

Figure 3.3: *Proportional differences (relative to the control shoe) in peak pressure (PP), maximal mean pressure (MMP) and force time integral (FTI) per mask for all four experimental conditions. Means of the experimental conditions were divided by the mean of the control shoe. Positive percentages indicate an increase in pressure compared to the control, while negative percentages indicate a decrease. Flex 50: Flexible rocker with apex positioned at 50%. Rigid 50: Rigid rocker with apex positioned at 50%. Flex 60: Flexible rocker with apex positioned at 60%. Rigid 60: Rigid rocker with apex positioned at 60%. #: Significant difference between the experimental conditions compared to control (p < 0.001). *: Significant difference between experimental conditions (p < 0.001).*

For the medial forefoot only Rigid 60 resulted in a significant decrease in PP compared to the control (p<0.001). No significant differences in PP were found between rocker configurations for this mask. In both the central and lateral forefoot a significant decrease in PP was found for all rockers when compared to the control (p<0.001). This was also found for MMP in the lateral forefoot, while in the central forefoot only rockers with the apex positioned at 50% resulted in a significant decrease in MMP (p<0.001). In both masks, rigid rockers resulted in significantly lower PP (p<0.001) and MMP (p<0.001) compared to flexible rockers.

PP was significantly increased at the heel in all rockers compared to the control (p<0.001). The increase was significantly larger (p<0.001) in rigid rockers compared to flexible rockers.

The results for VAS are shown in figure 3.4. All experimental conditions scored significantly lower on comfort than the control shoe (p<0.001). No differences were found between experimental conditions.

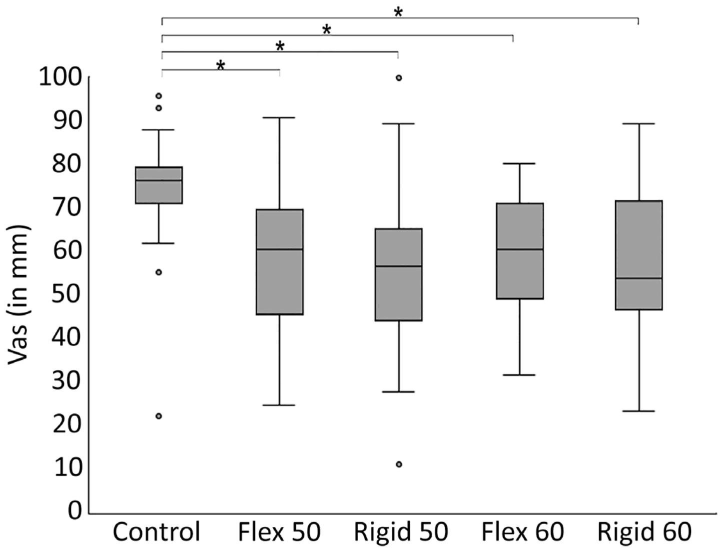

Figure 3.4: *Difference in comfort between conditions. Flex 50: flexible configuration, apex positioned at 50%, Rigid 50: rigid configuration, apex positioned at 50%, Flex 60: flexible all toes while for rigid rockers it is mainly distributed across the first configuration, apex positioned at 60% and Rigid 60: rigid configuration, apex positioned toe. We believe that the ground reaction force's point of application at 60%. *: significant difference (p < 0.005).*

Discussion

To the best of our knowledge this is the first study that evaluated the difference in plantar pressure between rigid and flexible rocker profile shoes that only allow dorsiflexion. Compared to the control shoe, rigid rockers showed larger plantar pressure reductions for the central and lateral forefoot than flexible rockers. For the medial forefoot, however, no differences were found and for the first toe, rocker shoes showed an increase in plantar pressure which was larger in rigid than in flexible rockers.

Compared to flexible rockers, a significantly larger increase in PP was found for rigid rockers for the first toe mask, where PP in rigid rockers were up to 26,5 kPa larger. While not significant, similar trends in effects were found in MMP and FTI. A similar increase in PP for rigid rockers with the apex positioned at 50% was found by van Schie et al. (2000) [10]. For the other toes there seemed to be a reduction in pressure compared to the control shoe. These findings were less pronounced than those of the first toe and were mainly supported by significant reduction in MMP for rigid rockers.

For both central and lateral forefoot masks, representing MTH2-5, a reduction in pressure was found which was more pronounced in rigid rockers as hypothesized, with differences in PP between 8.7 and 14.9 kPa. In contrast to previous studies[10,11], rigid rockers with an apex position at 50% resulted in a larger reduction than rockers with an apex position at 60%. There was hardly any change in pressure found compared to the control shoe for MTH1, which is represented by the medial forefoot mask. This is likely due to the apex angle (85°) which might be more suitable for offloading of MTH2-5 than for MTH1[11].

For the midfoot there seemed to be an increase in pressures compared to the control shoe. Especially in MMP for rockers with the apex positioned at 50% there seemed to be a large proportional increase. However, the largest absolute increase in MMP was only 6.6 kPa, and the largest increase in PP was 5.6 kPa. Similar to some other studies[10,11] an increase in PP was found for the heel, which in this study are most likely due to the replacement of the soft original sole with harder EVA, resulting in less absorption of the forces at heel strike. This is supported by the significant larger increase in PP found for rigid rockers where the forces interact with a carbon plate that is more rigid than the EVA replacement.

The outcomes for VAS for comfort showed that all rockers were significantly less comfortable than conventional shoes. Between rockers no significant differences were found, indicating that in terms of comfort it likely does not matter for novel users if they wear rigid or flexible rockers. However, these findings may not be applicable for long term use, as the participants walked on each condition for a short time.

The results found in the current study cannot directly be generalized to all patients with DM as only healthy volunteers participated. However, Chapman et al.(2013) showed that, despite differences in plantar pressure between healthy adults and low risk patients with DM, there are hardly any differences in the effect of the rocker variables between these groups[11]. Therefore, we consider the findings in this study to be very valuable for management of plantar pressure in patients with DM. Especially the findings for the first toe, that showed lower PP for flexible rockers compared to rigid rockers, give new insight in offloading of plantar pressures with rocker profiles as it concerns one of the high risk areas for ulcerations. These findings could be explained by the results found for the other toes, where a significantly larger reduction of MMP was found for rigid rockers compared to flexible rockers, while there were no differences in PP. This indicates that for rigid rockers there is less pressure in this mask suggesting that when toe dorsiflexion is allowed, plantar pressure is distributed across all toes while for rigid rockers it is mainly distributed across the first toe. We believe that the ground reaction force's point of application around push-off is forced towards the tip of the toe in rigid rockers as a result of the rocker features (apex position and apex angle), where in flexible rockers, because flexing of the shoe reduces the effects of these features, the point of application is shifted more towards the other toes.

For the first toe a flexible rocker may be the better choice, however, rigid rockers resulted in larger pressure reductions for the forefoot, which is also considered a high risk area. Depending on the areas at risk for each individual, determined by in-shoe pressure measurements, it can be decided what type of rocker suits best. Also, a hybrid between rigid and flexible rockers that allow toe dorsiflexion may result in better prevention of diabetic foot ulcers than completely rigid rockers.

There are some limitations to the current study. There was no real accommodation period before each condition, which might be needed with rocker shoes. Although the accommodation period was short, the data showed no systematic changes in pressures over the twelve measured steps within subjects, indicating no additional accommodation. Also, it would have been preferable to have used individually chosen apex angles, based on the foot progression angle of each individual. However, this would mean we had to make individual rockers for each subject. Another limitation is that the modified shoes were not equipped with a rubber sole to prevent slipping. Some of the participants' feet slid during push-off when they started walking, or when they slowed down at the end of the aisle. As only midgait steps were selected we expect that this will not have affected the outcomes. Finally, for four participants eleven steps were suitable for analysis where twelve are recommended when using Pedar-X®[14].

3

Conclusion

The current findings support the use of rigid rockers that restrict toe dorsiflexion for the reduction of plantar pressures at MTH2-5 but not for MTH1. For the first toe, restriction of toe dorsiflexion results in higher plantar pressures compared to rockers that do allow this motion. Further work is needed to evaluate if flexibility that allows dorsiflexion of the first toe also results in lower pressures for other apex angles and to evaluate the effects of a hybrid between rigid and flexible rockers that allow toe dorsiflexion.

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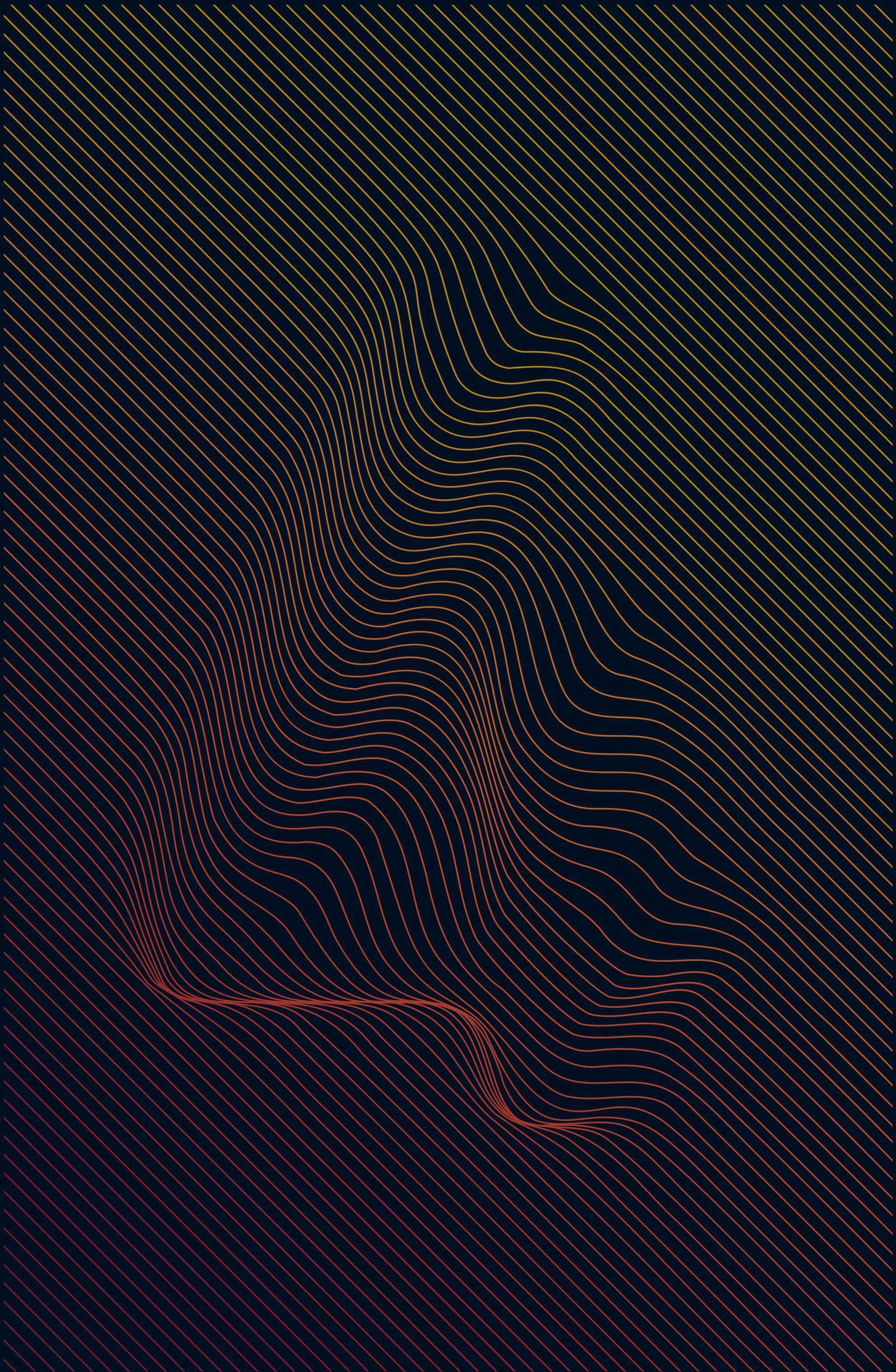

EFFECTS OF DIFFERENT ROCKER SETTINGS WITH A NEW ADJUSTABLE ROCKER PROFILE ON IN-SHOE PRESSURE

Abstract

Custom-made rocker profiles are commonly used to offload high risk areas of the foot to prevent diabetic foot ulcers. Due to changes in foot structures the areas at risk may change over time, which may result in insufficient offloading. To address this problem an adjustable rocker profile was developed. The effect of seven different apex settings (which were based on each individual's Metatarsal region) on in-shoe plantar pressure were evaluated in thirteen healthy male participants. Generalized Estimate Equation was used to test the effects between conditions. For the hallux three settings resulted in significantly lower peak pressures (PP) compared to the control ($p < 0.001$). At the medial forefoot PP were significantly decreased compared to the control ($p < 0.001$), where settings with increased apex angles resulted in the largest reduction. All settings resulted in lower PP ($p < 0.001$) when compared to the control at the central and lateral forefoot. Overall the adjustable rocker profile shows large reductions of in-shoe plantar pressure. To reduce pressures at the hallux the apex should not be located to proximate to the metatarsal region, and an increase in apex angle also seems effective, again when not placed to proximal. For offloading the medial forefoot the apex angle should be increased. Finally, at the central and lateral forefoot no specific setting will result in better offloading due to large variability between subjects.

R. Reints, J.H. Hijmans, K. Postema, G.J. Verkerke

Introduction

A common complication with Diabetes Mellitus (DM) is neuropathy[1]. A result, of neuropathy is lower to no protective sensory feedback from the feet[1,2]. Combined with increased plantar pressures, this puts DM patients with neuropathy at high risk of developing diabetic foot ulcers (DFU) that may eventually lead to amputation of the affected foot[3,4].

The metatarsal heads (MTH), and the hallux are considered high risk areas for DFU development as increased pressures mostly occur at these locations[5]. Rocker profiles are commonly used to reduce pressures at these areas[6,7]. Several design parameters that describe the roll over shape, including rocker axis, or apex, of a rocker profile can be altered to get the preferred pressure reducing effects[8-10]. One of these design parameters is the point where the rocker starts on the longitudinal axis, known as the apex position. The apex position is traditionally measured from the heel and presented as a percentage of the total shoe length. Another design parameter is the apex angle, which is the angle between the longitudinal axis and the apex of the rocker profile. [8-10]

In daily practice, rocker profiles are custom-made by removing the original outer sole of a shoe and adding new material, which is grinded into shape and stiffened. Often the shape of the rocker profile is not quantified, but based on the skills and experience of the orthopaedic shoe technician/pedorthist. As a result, most prescribed rockers do not optimally offload the areas at risk for each individual and due to changes in foot structures the areas at risk may change over time. Up to now there has not been a solution to change the rocker parameters without the tools and skills of the orthopaedic shoe technician/pedorthist.

An adjustable rocker profile was designed to overcome this problem. With the adjustable rocker profile it is possible to repeatedly change the apex position and apex angle within seconds. In the current study we want to evaluate the effect of different apex settings of the adjustable rocker profile, which are based on each individual's MTH region, on in-shoe plantar pressure. More specifically, we want to evaluate if different settings result in offloading of different areas of the foot to see if specific settings can be used for targeted offloading.

Based on previous findings we hypothesize that more proximal apex settings will result in more offloading of the overall MTH region but not the first toe[10]. Also, increasing the apex angle will result in more offloading of the medial side of the forefoot and the hallux, where decreasing the apex angle will result in more offloading of the lateral side of the forefoot[8].

Methods

Participants

Thirteen healthy male adults participated in this study. Inclusion criteria were male gender, age 18 years or older, and shoe sizes EU42-43. This subgroup was selected since the prototype was built using a size EU42.5 shoe. The use of custom inlays and self-reported pathologies or injuries that influence gait were considered exclusion criteria. All participants provided written informed consent before starting the experiments. The local Medical Ethics Committee determined that conduct of this study was not subject to the Medical Research involving Human Subject act (METc 2017.050).

Adjustable rocker profile

The prototype of the adjustable rocker profile shoe was made using a pair of Dr Comfort shoes (Chris, Dr Comfort, Mequon, WI, USA) of which the outer sole was cut off. The mechanism of the adjustable rocker profile shoe (see figure 4.1) consists of two rails and sliders, that allow for continuous adjustability of both the apex position and apex angle. The rails were integrated in each shoe's reinforcement by using three carbon layers. The top layer was used as support. The middle and bottom layer both had two cuts parallel to the longitudinal axis of the shoe that were 24mm and 8mm wide respectively. With the three layers of carbon, the sole is also stiffened. Two tee nuts with a diameter of 19mm functioned as sliders. Two 3D-printed knobs (30mm diameter, 13mm height) with tapered rims were screwed onto the tee nuts with a bolt. After loosening the bolts, the position of these knobs could be changed manually across the rails, after which the bolts were tightened again to secure the knobs in place. A layer of 3mm Polyethylene (Streifylast, Streifeneder, Emmering, Germany) was positioned between the original outer sole and knobs to prevent the knobs from digging into the outer sole.

At the heel 16mm thick Ethylene-vinyl acetate (EVA, 70 durometer, shore A) was attached to the bottom carbon layer to accommodate for the increase in height as a result of the carbon layers, knobs and Polyethylene. The original outer sole was glued to the added EVA. Finally, a Velcro strap was stitched to the nose to allow for quick access to the knobs.

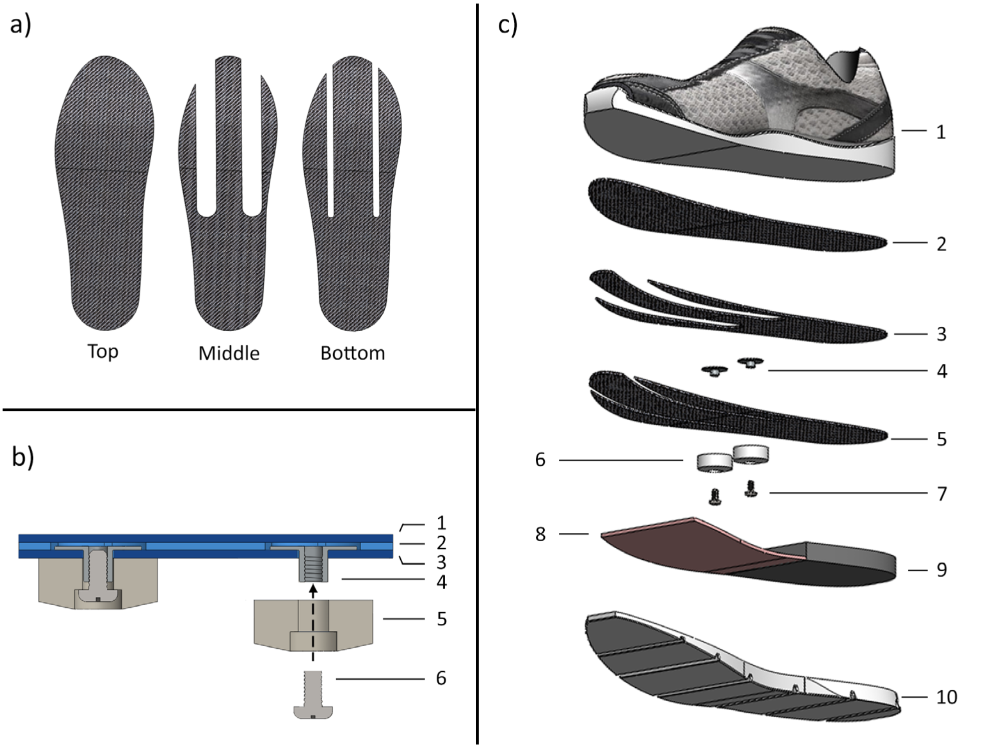

Figure 4.1: *Representation of the adjustable rocker profile assembly. a) The three carbon layers that were glued together to create the rail. b) Frontal cross section of the rail and slider mechanism (1: top carbon layer, 2: middle carbon layer, 3: bottom carbon layer, 4: tee-nut, 5: 3D-printed knob, 6: bolt). c) Exploded view of the adjustable rocker profile assembly (1: upper of the Dr Comfort Chris shoe, 2: top carbon layer, 3: middle carbon layer, 4: tee-nut, 5: bottom carbon layer 6: 3D-printed knobs, 7: bolts, 8: PE plate, 9: added EVA at the heel, 10: Original outer sole of the Dr Comfort Chris shoe).*

The two knobs, with the polypropylene plate and sole, functioned as a rocker profile, of which the apex was determined by an imaginary line that crosses the midpoint of both knobs. At an apex angle of 90˚, the prototype allowed for any apex position between 50% and 70%. The range of possible apex angles was 40˚ to 140˚.

Apex settings

For a more individualized approach the apex settings were based on the location of MTH1 and MTH5 in each individual. Three reference lines were drawn, see figure 4.2. The first, referred to as the 0% line, was drawn through MTH1 and MTH5. The other two reference lines were drawn parallel to that line at 5% and 10% of the total shoe length, proximal to the 0% line. A total of seven apex settings were tested (figure 4.2). Medial 0%, Lateral 0% (M0L0): both knobs at 0% line, M5L5: both knobs at 5% line, M10L10: both knobs at 10% line, M5L0: medial knob at 5%, lateral knob at 0%, M10L5: medial knob at 10%, lateral knob at 5%, M0L5: medial knob at 0%, lateral knob at 5%, and M10L5: medial knob at 10%, lateral knob at 5%.

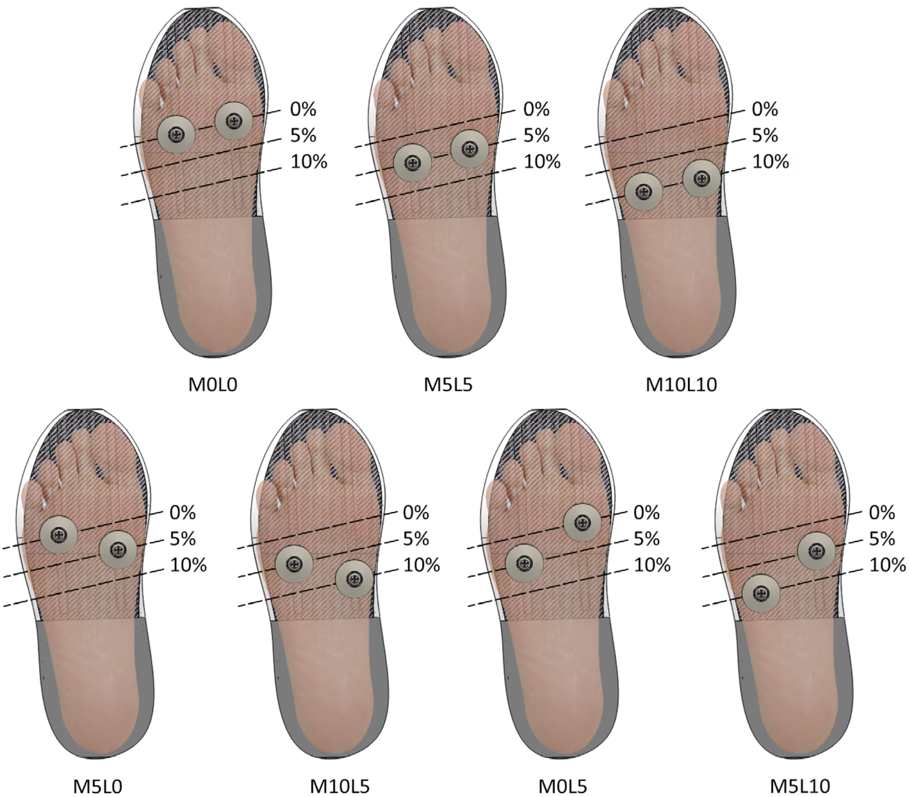

Figure 4.2: *Apex settings. The dotted lines show the reference lines based on the location of MTH1 and MTH5.*

In-shoe pressure measurements

To measure in-shoe plantar pressure Pedar-X® insoles were used. The insoles were calibrated before the study using the Trublu (Novel; Munich, Germany) calibration device. Data were collected from both feet at a sampling frequency of 100Hz.

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Experimental procedures

All experimental procedures were performed at the Motion Lab of the Department of Rehabilitation Medicine, University Medical Center Groningen. Height and bodyweight were determined before the experiments started. MTH 1 and 5 were located through palpation and lines were drawn on the medial and lateral side of the shoe to indicate both locations. All participants wore the same type of seamless socks (Ankle socks, Dr Comfort, Mequon, WI, USA). First, each participant walked ten times across the 10 meter aisle of the Motion Lab, wearing their own flat soled shoes they were instructed to bring. Walking speed was measured using the Speedclock app (Sten Kaiser, v10.4). The median of the last three measurements was considered the preferred walking speed. Walking speed in following trials needed to be within a ± 10% range of the preferred walking speed.

All seven apex settings were measured in a randomized order and the experiment ended with a reference measurement using an unmodified pair Dr Comfort Chris shoes. For each setting participants first walked ten times across the lab for accommodation, after which they walked another five times for the in-shoe pressure measurements. The Pedar-X system was zeroed after donning the control shoe and after donning the adjustable rocker profile. Between apex settings Pedar-X was not zeroed, as changing the apex setting did not require doffing and donning of the adjustable rocker.

Data analysis

Due to some missing data from the right Pedar insole only data from the left leg were analyzed. For each trial three midgait steps were selected using Pedar-X® Step analysis (Novel; Munich, Germany), resulting in a total of fifteen steps for each condition. The first twelve midgait steps[11] without missing data were selected for further analysis using Matlab (R2016a). The sensors of the Pedar-X® insole were divided into seven masks (figure 4.3) representing: 1) hallux, 2) other toes, 3) medial forefoot, 4) central forefoot, 5) lateral forefoot, 6) midfoot and 7) heel[10,12]. Peak pressures (PP) were selected within each mask for every step. Maximal mean pressures (MMP) were determined by first calculating the mean pressure for each mask for all timeframes within a single step, after which the timeframe with the maximum mean pressure was selected for every step. Finally, force time integral (FTI) was determined as the area under the force curve for each sensor within a mask.

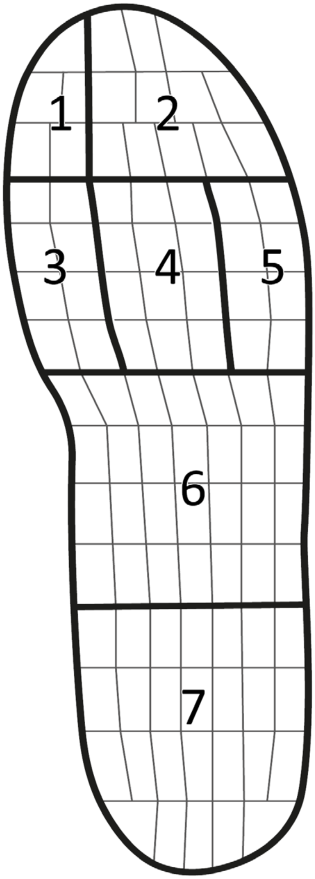

Figure 4.3: *99 sensors of Pedar-X divided into seven masks representing 1) Hallux, 2) Other toes, 3) Medial forefoot, 4) Central forefoot, 5) Lateral forefoot, 6) Midfoot, and 7) Heel.*

Statistical analysis

Means and standard deviations were determined to describe study population characteristics. PP, MMP and FTI were analysed separately using generalized estimate equation (GEE) with shoe condition, mask and step as within subject variables estimating the response of the shoe conditions. All statistical analyses were performed using SPSS statistics (23.0.0.0). For both overall tests the level of significance was set at $p<0.05$. For pairwise comparison using GEE Bonferroni correction was applied, resulting in a level of significance set at $p<0.001$.

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Results

The participants had a mean (±SD) age of 21 (±2) years, bodyweight of 78.3 (±9.0) kg, and body height of 1.82 (±0.06) m. The average walking speed was 1.54 (±0.19) m/s. Table 4.1 shows all means and 95% confidence intervals (CI) for PP, MMP, and FTI. Between conditions significant differences were found PP ($p < 0.001$), MMP ($p < 0.001$) and FTI ($p < 0.001$). Figure 4.4 shows the relative changes for all rocker settings relative to the control shoe. Below only relevant findings for the hallux, medial, central, and lateral forefoot are described, as these are considered at high risk for ulcerations.For the hallux the settings M0L0, M5L5, and M5L0 resulted in significant lower PP ($p<0.001$) compared to the control shoe, with no significant differences between these three settings. There were no significant differences in MMP and FTI compared to the control.

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At the medial forefoot mask all apex settings with exception of M0L5 resulted in significantly lower PP compared to the control ($p<0.001$). Significantly lower PP ($P<0.001$) were found between the apex setting with larger apex angles (M5L0 and M10L5) compared to those with smaller apex angles (M0L5 and M5L10). Compared to M0L0 lower PP were found in M5L5 and M5L0 ($p<0.001$). Significantly increased MMP ($p<0.001$) were found in M0L5 and M5L10 compared to the control, M5L0, and M10L5. For the medial forefoot no significant changes in FTI were found in any of the settings compared to the control shoe.

For the central forefoot mask all apex settings showed significantly lower PP compared to the control shoe ($p<0.001$), but no differences between settings were found. MMP was significantly lower ($p<0.001$) in M5L5, M5L0, M10L5, and M0L5 for this mask. FTI was only significantly lower ($p<0.001$) in M10L10 and M10L5 compared to the control shoe.

Finally, at the lateral forefoot mask, all apex settings showed significantly lower PP, MMP, and FTI compared to the control. For PP only a significant difference between M5L5 and M0L5 ($p<0.001$) was found, where M0L5 resulted in a larger reduction.

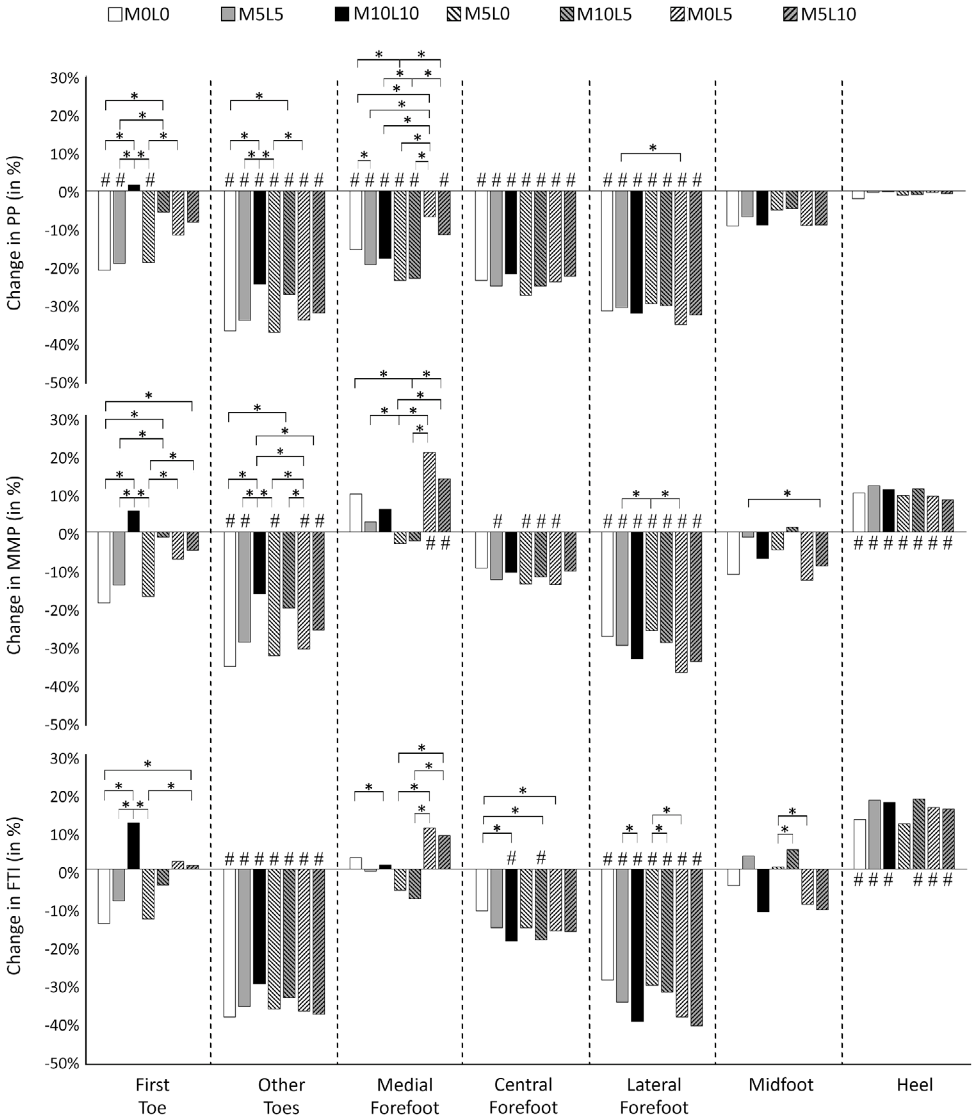

Figure 4.4: *Relative changes in peak pressure (PP), maximal mean pressure (MMP) and force time integral (FTI) for each apex setting across all masks. Means of the apex settings were divided by the mean of the control shoe. Positive percentages indicate an increase in pressure compared to the control, while negative percentages how a decrease. #: Significant difference compared to control (p < 0.001). *: Significant difference between apex settings (p < 0.001).*

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Table 4.1: *Absolute values of all in-shoe outcome parameters for all rocker settings. CI: Confidence interval. PP: Peak Plantar Pressure. MMP: Maximum Mean Pressure. FTI: Force-time integral. FF: Forefoot.*

	Control	M0L0	M5L5	M10L10	M5L0	M10L5	M0L5	M5L10
	mean [95% CI]	mean [95% CI]	mean [95% CI]	mean [95% CI]	mean [95% CI]	mean [95% CI]	mean [95% CI]	mean [95% CI]
PP (kPa)								
Hallux	193 [162 ; 224]	154 [121 ; 187]	157 [126 ; 188]	196 [155 ; 237]	157 [122 ; 192]	183 [144 ; 221]	171 [131 ; 211]	178 [139 ; 217]
Other toes	162 [144 ; 181]	103 [89 ; 118]	107 [90 ; 124]	123 [104 ; 141]	103 [88 ; 117]	119 [100 ; 138]	108 [93 ; 122]	111 [98 ; 124]
Medial FF	209 [184 ; 234]	177 [153 ; 201]	169 [145 ; 192]	172 [150 ; 194]	160 [138 ; 181]	162 [140 ; 183]	195 [169 ; 220]	185 [162 ; 209]
Central FF	230 [213 ; 247]	177 [154 ; 200]	173 [152 ; 194]	180 [160 ; 200]	168 [148 ; 187]	173 [152 ; 194]	176 [152 ; 199]	179 [160 ; 198]
Lateral FF	164 [135 ; 194]	113 [101 ; 126]	115 [104 ; 125]	112 [100 ; 125]	116 [101 ; 132]	115 [100 ; 130]	108 [96 ; 119]	111 [97 ; 126]
Midfoot	90 [81 ; 98]	82 [72 ; 92]	84 [74 ; 94]	82 [71 ; 92]	85 [77 ; 94]	86 [76 ; 95]	82 [73 ; 90]	82 [72 ; 91]
Heel	234 [220 ; 248]	229 [208 ; 250]	233 [213 ; 253]	234 [214 ; 253]	232 [210 ; 255]	231 [211 ; 251]	233 [213 ; 254]	232 [211 ; 253]
MMP (kPa)								
Hallux	124 [100 ; 149]	102 [81 ; 124]	108 [86 ; 130]	131 [105 ; 156]	104 [81 ; 126]	123 [97 ; 148]	116 [91 ; 141]	119 [95 ; 142]
Other toes	77 [66 ; 89]	52 [43 ; 60]	56 [46 ; 66]	65 [55 ; 76]	53 [46 ; 61]	63 [52 ; 73]	55 [47 ; 62]	58 [51 ; 65]
Medial FF	106 [91 ; 121]	116 [100 ; 132]	108 [91 ; 126]	112 [91 ; 132]	103 [87 ; 118]	104 [88 ; 120]	127 [110 ; 144]	120 [103 ; 137]
Central FF	120 [106 ; 134]	109 [99 ; 120]	105 [94 ; 117]	108 [95 ; 121]	104 [93 ; 116]	106 [94 ; 119]	104 [94 ; 115]	108 [96 ; 121]
Lateral FF	99 [78 ; 119]	73 [64 ; 81]	70 [63 ; 78]	67 [58 ; 76]	74 [65 ; 84]	71 [60 ; 82]	64 [55 ; 72]	66 [56 ; 77]
Midfoot	31 [26 ; 36]	28 [23 ; 33]	31 [26 ; 36]	29 [24 ; 34]	30 [25 ; 35]	32 [27 ; 36]	27 [23 ; 31]	29 [24 ; 33]
Heel	125 [119 ; 131]	137 [127 ; 147]	139 [130 ; 149]	138 [129 ; 148]	137 [126 ; 148]	138 [128 ; 148]	136 [126 ; 147]	135 [125 ; 145]
FTI (N*s)								
Hallux	21 [15 ; 26]	18 [13 ; 22]	19 [14 ; 23]	23 [18 ; 28]	18 [13 ; 23]	20 [15 ; 25]	21 [16 ; 26]	21 [16 ; 26]
Other toes	41 [32 ; 51]	25 [20 ; 31]	27 [20 ; 33]	29 [22 ; 35]	26 [20 ; 32]	27 [21 ; 34]	26 [20 ; 32]	26 [22 ; 30]
Medial FF	45 [36 ; 54]	46 [36 ; 57]	45 [34 ; 55]	45 [35 ; 56]	42 [33 ; 52]	41 [32 ; 51]	50 [39 ; 60]	49 [39 ; 59]
Central FF	87 [74 ; 99]	77 [65 ; 90]	73 [61 ; 86]	71 [58 ; 83]	73 [61 ; 86]	71 [58 ; 83]	73 [60 ; 85]	73 [59 ; 86]
Lateral FF	52 [39 ; 64]	37 [30 ; 44]	34 [28 ; 39]	31 [25 ; 37]	36 [29 ; 43]	35 [27 ; 43]	32 [25 ; 39]	31 [24 ; 37]
Midfoot	49 [37 ; 62]	47 [38 ; 56]	51 [42 ; 60]	44 [37 ; 51]	50 [42 ; 57]	52 [43 ; 61]	45 [39 ; 51]	44 [37 ; 51]
Heel	128 [113 ; 143]	145 [134 ; 156]	152 [141 ; 162]	151 [139 ; 163]	144 [134 ; 154]	152 [140 ; 164]	149 [136 ; 162]	149 [137 ; 160]

Discussion

The aim of this study was to evaluate the effect of seven personalized apex settings with the adjustable rocker on plantar pressures and to see if specific settings would result in offloading of specific areas that are at risk of ulcerations. For the hallux three settings (M0L0, M5L5, and M5L0) were found to significantly decrease PP. There were no significant differences between these three settings. For the medial forefoot, settings with a smaller apex angle (M0L5, M5L10) resulted in significantly less reduction of PP. The best results for this mask are found in settings with increased apex angles (M5L0, M10L5). For both the medial and central forefoot all settings significantly decreased PP compared to the control shoe, but between settings no differences were found.

As hypothesized, more proximal settings resulted in less offloading at the hallux. Although no significant differences were found between M0L0 and M5L5, an increase in PP was found in M10L10 which was around 40 kPa larger compared to both M0L0 and M5L5. Also, increasing the apex angle can effectively reduce PP at the hallux, but again only when the apex is not positioned too proximal.

As expected for the medial forefoot, the use of larger apex angles (M5L0, M10L5) result in significantly lower PP compared to smaller apex angles (M0L5, M5L10) with differences between 23.7 and 34.8 kPa. However, more proximal settings will not always result in reduced PP. There seems to be a limit between 5% and 10% proximal to the MTHs, as M5L5 resulted in significantly lower PP than M0L0 while M10L10 seems to be less effective than M5L5.

In the central and lateral forefoot all settings significantly reduced PP compared to the control. There were no significant differences between conditions to confirm the hypothesis stating more proximal apex settings result in smaller PP for the forefoot region. This can be explained by the large differences between individuals. While within subjects there were some large differences in PP for different apex settings, the between subjects variability was too big to find any significant differences.

Other studies also reported large between subject variability in optimal rocker settings[8,9]. By basing the apex settings on each individual's MTH location, we hoped to find more differences between settings, which would indicate what specific setting would be best for offloading PP in certain high risk areas. The fact that these differences were not as pronounced as expected on group level, while in some cases large differences between settings were found, highlight the complexity of finding the right rocker profile design for each individual.

The described adjustable rocker profile could make it easier to find the right rocker design for each individual, as the rocker parameters can quickly be changed. During a test session with an in-shoe pressure measurement system like Pedar-X three or more (depending on the targeted area) settings could be measured and the setting with the best reductions in PP could be used when making a conventional rocker profile.

There are some limitations to the design of the adjustable rocker profile and the current study. Because of the added rail and slider mechanism the adjustable rocker profile (525 g) weighs 87,5% more than the unmodified shoe (280 g). While none of the participants needed extra time between conditions to recover, the increased weight could result in fatigue when walking on the adjustable rocker for a longer period of time. However, a study that examined rocker profile shoes with similar weight (507 ± 89,7 g) showed no increase in energy cost while walking[13]. Also, because of the hole in the knobs, which are needed to keep the bolts flush, the actual rollover point might not be exactly in the middle of the knob but up to 6 mm (2% of the total shoe length) more distally. While this would not affect future work with the current adjustable rocker it might affect translation to other rocker profiles designs.

The results from the current study cannot be directly generalized to patients who are at high risk of ulcerations, as only healthy adults participated without (self-reported) foot problems. Therefore, the adjustable rocker should be further tested in patients with diabetes and neuropathy.

Conclusion

Overall the adjustable rocker profile shows large reductions of in-shoe plantar pressure. For reducing pressures at the hallux the apex should not be located to proximate to the MTH region, and an increase in apex angle can also be effective. For the medial forefoot, settings with a larger apex angle show the best pressure reductions, while for the central and lateral forefoot all settings significantly reduce pressure.

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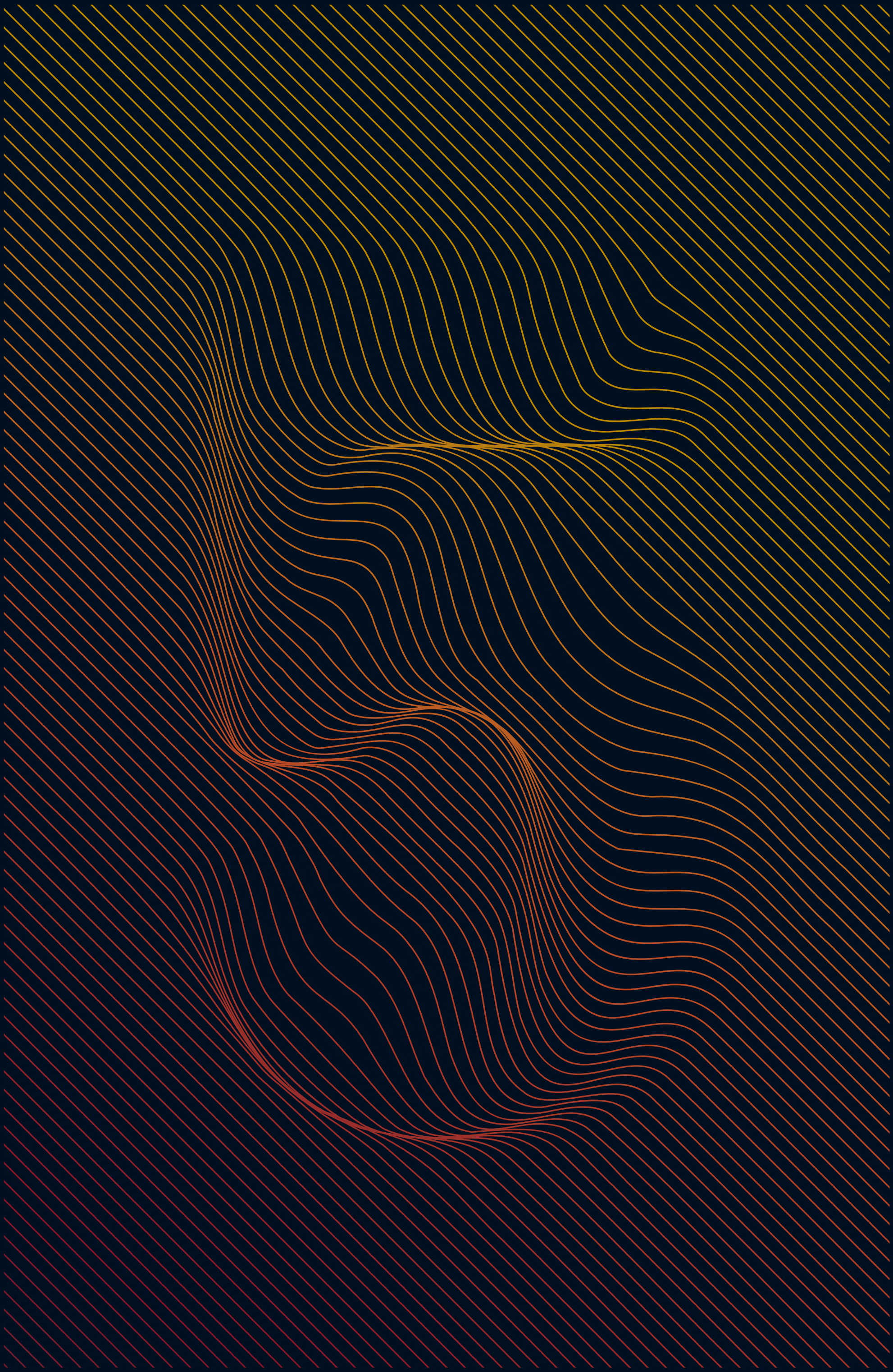

DESIGN AND TEST OF A NOVEL SELF-ADJUSTING INSOLE TO REDUCE IN-SHOE PEAK PRESSURES

Abstract

A self-adjusting insole was designed for the prevention of diabetic foot ulcers. The insole consists of elements which have a supporting surface that drops down only when pressures are above a certain pressure threshold (*$Threshold_{in}$*) allowing for offloading by redistribution across neighboring elements, while avoiding negative effects on balance. In the current study *$Threshold_{in}$* was determined both mechanically with a force versus displacement measurement, and during walking using in-shoe pressure data collected from healthy subjects (n=15). Also, the number of sensors showing peak pressures (PP) over 200 kPa and largest PP for both configurations were compared to a control inlay. The stiff configuration (*$Threshold_{in}$* = 253 kPa), showed a significant ($p < 0.001$) increase in both the number of sensors over 200 kPa and the largest PP. With the flexible configuration, (*$Threshold_{in}$* = 144 kPa), it was possible to significantly reduce the number of sensors with PP over 200 kPa in the control configuration ($p = 0.007$). Although *$Threshold_{in}$* was considered too high in the stiff, and too low in the flexible configuration, the self-adjusting insole showed great potential in reducing in-shoe PP.

R. Reints, J.M. Hijmans, K. Postema, G.J. Verkerke

Introduction

A major complication in patients with diabetes is peripheral sensory neuropathy. Due to little or no protective feedback, high pressure spots at the plantar surface of the feet remain unnoticed[1-3]. As a result, these patients are at high risk of developing difficult to heal diabetic foot ulcers (DFU) which can eventually lead to amputation of the affected lower limb[4,5].

Custom-made pressure reducing insoles are commonly prescribed in the prevention of DFU, aiming to lower peak pressures (PP) below 200 kPa[6] or, when PP below 200 kPa cannot be achieved, by at least 30%[7]. The shape and materials used in these insoles are mainly based on the skills and experience of the orthopedic shoe technician[8]. While custom-made insoles initially result in good offloading, structural wear and tear over time may result in insufficient offloading[9]. Also, changes in foot structures[10,11] can result in insufficient offloading as the location of pressure spots may have changed over time.

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The way pressure is redistributed is very important. While a compliant insole surface that changes along with the foot at any time like gels or other highly resilient materials might seem promising for redistribution of PP, they negatively affect stability, balance, and tactile sensation from the plantar surface of the foot[12]. This especially becomes a problem in patients who have developed sensory neuropathy, as their tactile sensation is already decreased. Therefore, the insole should only offload at the location where PP are considered too high, but should provide sufficient support at the locations where the pressure stays within the safe margins. Therefore, in order to adjust to the changing pressure spots a dynamic pressure redistributing insole is needed.

A novel self-adjusting insole that locally adjusts to pressures above a safe threshold was developed. The self-adjusting insole consists of elements which have a supporting surface that, as a result of buckling, drops down only when pressures are above a certain pressure threshold ($Threshold_{in}$). When the supporting surface of the elements drops down, pressure is offloaded locally and redistributed to neighbouring elements, meaning that the pressure is reduced at the location of the element that buckled while it is increased (up to $Threshold_{in}$) at the location of the surrounding elements. As PP over 200 kPa are considered dangerous for those at risk of DFU, the

$Threshold_{in}$ should be below 200 kPa to reduce these dangerous PP. After buckling, the element returns to its original shape when the pressure gets below a second pressure threshold ($Threshold_{out}$), which is the result of the element's elasticity and is always lower than $Threshold_{in}$. This is thought to happen during the swing phase. As the self-adjusting insole is made entirely out of these elements, it ensures offloading even when the location of high pressure changes over time.

The aim of the current study was to explore the characteristics and functionality of the self-adjusting insole concept both mechanically and during walking using two self-adjusting insole configurations and a control insole made out of soft Ethylene vinyl acetate (EVA). During walking the focus will be on PP at the first toe and forefoot, as these areas are considered at high risk for ulcerations. We hypothesize that PP below the $Threshold_{in}$ of the self-adjusting insole configurations will be higher in the self-adjusting insole conditions compared to the control condition where a more compliant inlay was used. When PP is over the $Threshold_{in}$ in the control condition, PP in the self-adjusting insole conditions is expected to be lower at these locations. Also, we hypothesize that a $Threshold_{in}$ below 200 kPa will result in a decrease in PP over 200 kPa while a $Threshold_{in}$ over 200 kPa will not.

Methods

Insole design

Each self-adjusting insole consists of 105 hexagonal shaped elements across the entire insole surface (figure 5.1a). Each element (figure 5.1b) has a top surface of 1.46 cm2 and a height of 9 mm. The elements buckle when a pressure over a certain threshold is applied ($Threshold_{in}$) and will return to their original shape when a returning threshold ($Threshold_{out}$) which is lower than $Threshold_{in}$, is reached. When the element buckles, the surface of the element that is in contact with the foot drops down approximately 3.5 mm, which results in a lowering of the plantar pressure at the location of that element and a pressure redistribution across neighboring elements.

Pilot-work showed that the thresholds can be changed by adjusting the wall thickness (T_{wall}) and the angle (α) of the lower part of the element (figure 5.1c). Increasing these parameters will result in an increase of the thresholds. Based on this pilot work two insole configurations were used, a flexible and a stiff configuration. For the flexible insole configuration T_{wall} was 0.9 mm, for the stiff configuration T_{wall} was 1.2 mm. The angle α was 50 degrees in both configurations.

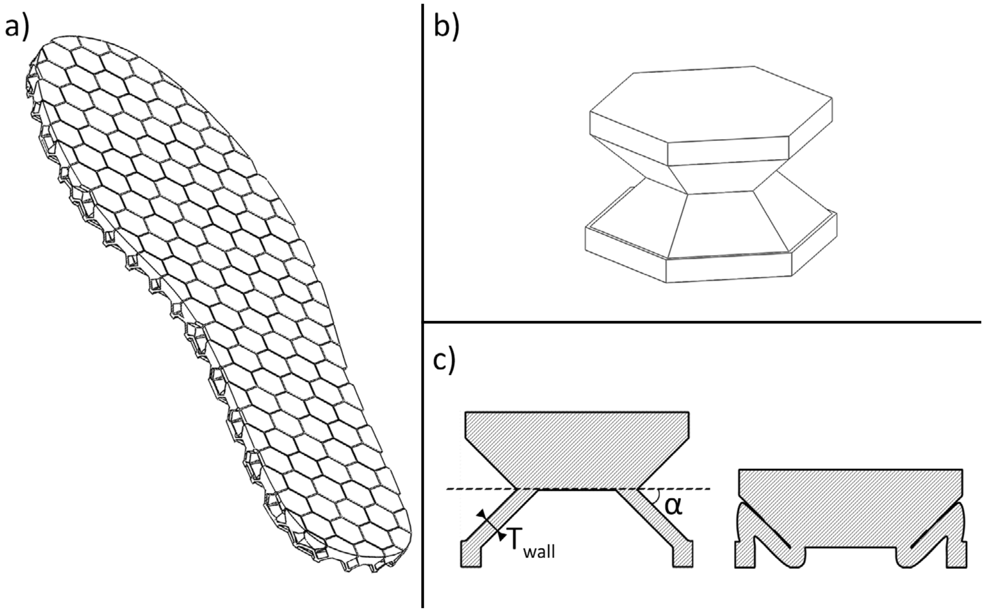

Figure 5.1: The self-adjusting insole (a) which consists of 105 hexagonal shaped elements (b). These elements buckle when pressures are above a certain threshold (c). The threshold can be adjusted by altering the thickness Twall and the angle α.

The height of the insoles was 9 mm. The other dimensions were based on the shape of the innersole of the shoes in which the insoles were tested (Chris size 42,5 EU, Dr Comfort, Mequon, WI, USA). The insoles were 3D-printed with fused deposition modeling (FDM) printers using flexible filament (Ninjaflex, Thermoplastic Polyurethane, 85 durometer shore A). For the control configuration the 6 mm Ethylene vinyl acetate (EVA, 25 durometer, shore A) inlays that came with the shoes, were elevated by placing 3 mm cork underneath to get the same height as the self-adjusting insoles.

Mechanical tests

A custom test setup (figure 5.2) was used to mechanically determine the thresholds for both insole configurations. Force and displacement were measured using a force plate (sample frequency 1000 Hz) and Vicon motion capture system (sample frequency 200 Hz, 2 markers). The force plate was zeroed with the insole on top. Force was applied perpendicular to the surface of one element of the self-adjusting insole manually with a realistic speed until it buckled. After buckling, force was gradually removed until the element was restored to its original shape. This cycle was performed ten times for both configurations.

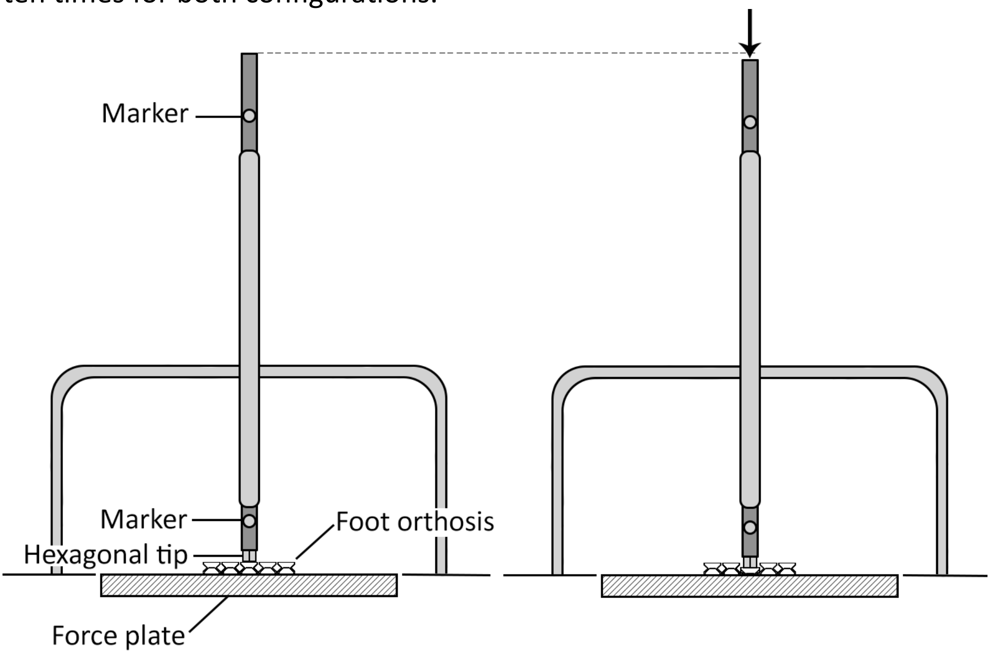

Figure 5.2: *Measurement setup used to determine force and displacement. Force was applied to the top of the dark grey cylinder which slides inside the light grey cylinder to keep the applied force perpendicular and centered to the supporting surface of the insole's element. Displacement of the two markers was measured using the ten infrared cameras of the Vicon motion capture system at 200 Hz. Force was measured using the force plate at 1000 Hz.*

Data analysis mechanical tests

To get as close as possible to the loading impulse during walking the five cycles of which the time from the initial force application until the maximal vertical displacement was closest to 0.3 sec were selected. 0.3 sec is approximately the duration between midstance and toe off in healthy adults (~30 % of one stride[13], stride time 0.99 s[14]), during which most of the forefoot loading is expected. This was selected as the focus is on pressures at the forefoot and toes.

All peaks were determined in a displacement ranging from 0 mm to 3 mm to exclude the increase in force after maximal displacement. $Threshold_{in}$ was determined as the mean peak force of the five selected cycles at which

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buckling occurred. *Threshold*$_{out}$ was calculated as the mean peak force measured when the original shape was restored. The mean forces (N) were divided by the supporting surface area (m^2) of the element to calculate the pressure (Pa).

In-shoe pressure measurements

Fifteen healthy male adults (age: 23 ± 4 years, bodyweight: 75.6 ± 7.8 kg, and height: 1.80 ± 0.05 m) participated in this study. Inclusion criteria were male gender, age 18 years or older, and shoe sizes EU42-43. Exclusion criteria were the use of custom insoles and self-reported pathologies or injuries that influence gait. All participants provided written informed consent before starting the experiments. The current study was part of a larger study which was not subject to the Medical Research involving Human Subject act according to the ethics committee of the University Medical Center Groningen (METc 2017/603).

Pedar-X (Novel; Munich, Germany) was used to measure in-shoe pressure. The insoles were calibrated according to manufacturer's instructions. Sampling frequency was set at 100Hz. Measurements were performed at the Motion Lab of the Department of Rehabilitation Medicine, University Medical Center Groningen. Height, bodyweight, and preferred leg were determined before the experiments started. All participants wore the same type of socks (Ankle socks, Dr Comfort, Mequon, WI, USA). Every participant was asked to walk in three different conditions, the control, the flexible, and the stiff insole configuration, always with the Pedar-X system, in both shoes. The control condition was the first condition for each participant as preferred walking speed was determined during this measurement using the Speedclock application (Sten Kaiser, v10.7)[15,16]. Walking speed during the next conditions needed to be within ±10% of the preferred walking speed. The order in which the two self-adjusting insole configurations were tested, was randomly assigned. Before each condition Pedar-X was zeroed.

Prior to each measurement participants were asked to walk the 10m aisle of the motion lab ten times to get used to the footwear configuration. After adaptation, participants walked another five times across the aisle during which the in-shoe plantar pressures were measured.

Data analysis in-shoe pressure measurements

For the in-shoe pressure measurements, only data from the dominant leg were analysed. For each trial three midgait steps were selected using Pedar-X® Step analysis (Novel; Munich, Germany) resulting in maximal fifteen midgait steps per condition to account for possible missing data. The first twelve midgait steps were selected for further calculations as recommended[17]. Peak pressures (PP) were calculated for each sensor within the first toe, the medial forefoot, central forefoot, and lateral forefoot (33 sensors, see figure 5.3), as these represent areas of the foot that are at largest risk for ulcerations. PP were determined by selecting the highest measured pressure within a step for each of the sensors and calculating the mean across all twelve steps for each subject.

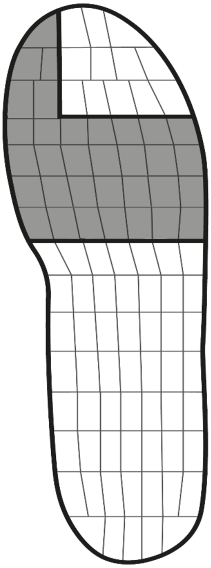

Figure 5.3: *99 sensors of Pedar-X. The 33 sensors that represent the first toe and forefoot area (grey) are used for data analysis in the current study.*

To determine the $Threshold_{in}$ during walking, PP data for the 33 sensors for all fifteen subjects (495 datapoints for each condition) were first sorted by the control configuration from low to high and then (in case of the same outcome for multiple datapoints) by the insole condition. After sorting, the difference in PP between the control and both self-adjusting insole configurations were calculated by deducting the PP in the control configuration from the PP in the self-adjusting insoles. Positive values indicated an increase in PP compared to the control while negative values indicated a decrease. The $Threshold_{in}$ for both self-adjusting insole configurations were determined as the point from where most negative difference values were found, as it is expected that PP will increase until the $Threshold_{in}$ is met, after which PP will decrease.

Finally, for each subject the number of sensors with PP over 200 kPa and the largest PP were determined in the first toe and forefoot area. This was chosen over comparing mean PP across all 33 sensors because of the working mechanism of the self-adjusting insole, which is only offloading PP over $Threshold_{in}$ by redistributing to neighboring elements. As a result of this working mechanism, it is likely that mean PP would not, or hardly, change.

Statistical analysis

To statistically test differences in 1) PP lower than the found $Threshold_{in}$, 2) PP higher than the found $Threshold_{in}$, 3) number of sensors over 200 kPa, and 4) largest PP between conditions first Friedman's ANOVA was used, with the level of significance set to $p < 0.05$. For pairwise comparison between the control and both experimental conditions Wilcoxon signed rank tests were performed. To account for the number of tests the level of significance was set to $p < 0.025$. All tests were performed using SPSS (IBM, v22.0).

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Results

Mechanical test

The mean ± SD thresholds for the flexible insole configuration were $Threshold_{in}$ = 21.0 ± 0.29 N (or 144 ± 2.01 kPa) and $Threshold_{out}$ = 8.6 ± 0.59 N (or 59 ± 4.0 kPa). For the stiff insole configuration a $Threshold_{in}$ = 36.9 ± 0.54 N (or 253 ± 3.7 kPa) and $Threshold_{out}$ = 13.7 ± 0.30 N (or 93 ± 2.1 kPa). The mean ± SD time of reaching maximum displacement for the loading cycles for the flexible configuration was 0.32 ± 0.07 s for the stiff configuration this was 0.31 ± 0.04 s. The force versus time graph in figure 5.4 shows the differences in characteristics between the control condition and the elements of the flexible and stiff self-adjusting insole configurations.

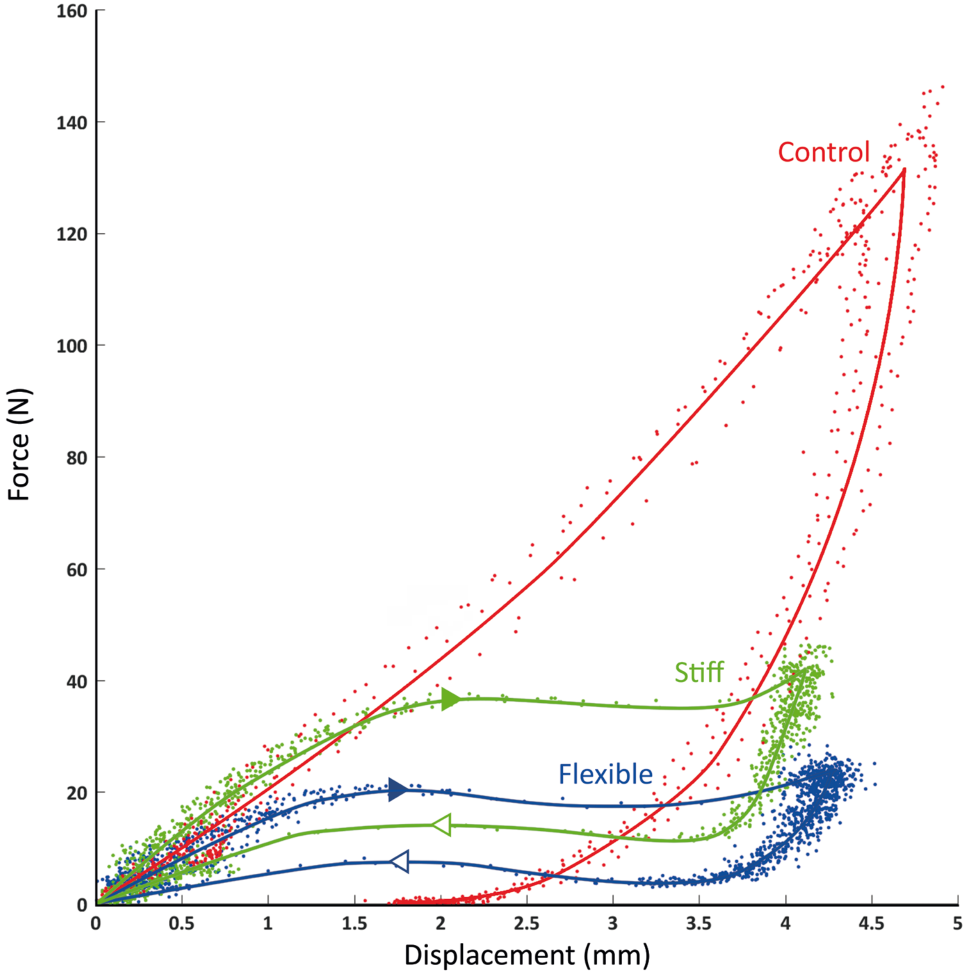

Figure 5.4: *Force versus displacement graphs of the control (red), flexible self-adjusting insole configuration (blue), and stiff self-adjusting insole configuration (green). Threshold$_{in}$ (solid arrows) and Threshold$_{out}$ (open arrow) for both the stiff and flexible insole configurations are indicated in the graph. Note that there are no thresholds for the control. The increase in force after 3 mm in both the flexible and stiff configuration was due to reaching the maximal displacement of the element*

In-shoe pressure measurements

Fig 5.5 shows the difference in PP compared to the control for both the flexible (figure 5.5a) and the stiff insole (figure 5.5b). For the flexible insole the value where the increase in PP changes to a decrease in PP, indicating

$Threshold_{in}$ during walking, seems to occur at a PP of 148 kPa (vertical dashed line). PP below the found $Threshold_{in}$ was significantly higher in the flexible insole compared to the control (Z = -13.817, p < 0.001) while PP above the threshold were significantly lower (Z = -5.306, p <0.001). For the stiff insole no clear $Threshold_{in}$, was found thus the difference in PP above and below the threshold could not be tested.

Table 5.1: *The number of sensors with PP over 200 kPa and the largest PP measured while walking with the control, flexible, and stiff self-adjusting insole configurations for each sub¬ject (n=15). The numbers in bold indicate a significant difference compared to the control (p < 0.025).*

	Control		Flexible		Stiff	
Subject number	Sensors >200 kPa	Largest PP	Sensors >200 kPa	Largest PP	Sensors >200 kPa	Largest PP
13	0	179	0	178	4	209
10	0	194	0	181	3	221
9	0	196	0	189	6	220
7	1	205	0	176	6	234
3	5	206	0	179	7	245
12	3	208	3	233	6	233
2	1	209	1	208	4	246
15	3	210	0	197	8	245
1	3	218	3	230	7	246
5	4	234	2	248	6	282
14	4	244	2	285	9	270
11	4	254	3	223	8	228
8	6	258	5	249	12	258
6	5	260	4	243	9	273
4	8	275	5	277	8	296
	3,1	*223*	***1,9***	*220*	***6,9***	***247***

Figure 5.5a and 5.5b also show that there are PP over 200 kPa in both insole configurations. The number of sensors that measured PP over 200 kPa and the largest PP found in these sensors are shown for the control, flexible, and stiff insole for each subject in table 5.1. Friedman's ANOVA showed a significant difference between conditions in number of sensors over 200 kPa (p < 0.001) and in largest PP (p < 0.001). Post hoc analysis showed for the flexible insole configuration that the number of sensors with pressures over

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200 kPa was significantly reduced in the flexible insole configuration (p = 0.007) while no significant reduction in largest PP was found (p = 0.334). For the stiff insole configuration there was a significant increase in both the number of sensors over 200 kPa (p = 0.001) and the largest PP (p = 0.003).

Discussion

The current study evaluated the offloading characteristics of a newly developed self-adjusting insole designed to offload pressures above a certain threshold. The thresholds for two insole configurations (flexible and stiff) were investigated using both force vs displacement measurements and in-shoe pressure measurements. For clinical relevance PP over 200 kPa were further examined. As hypothesized PP below the threshold where significantly higher in the flexible insole compared to the control. Moreover, the flexible insole showed a significant decrease in number of sensors over 200 kPa while the stiff insole configuration showed a significant increase.

The force versus displacement graph (figure 5.4) clearly shows the mechanical differences between both insole configurations and the control as the force decreases in both insole configurations after it reaches a certain level, or threshold, while the force continues to increase in the control up to maximal displacement. These thresholds were found when the displacement was increased from 0 until maximal displacement ($Threshold_{in}$) and while returning to 0 again ($Threshold_{out}$) for both insole configurations. The flexible insole had a $Threshold_{in}$ of 144 $\pm$ 2.0 kPa and a $Threshold_{out}$ of 59 $\pm$ 4.0 kPa while the stiff insole configuration had a $Threshold_{in}$ of 274 $\pm$ 3.7 kPa and a $Threshold_{out}$ of 114 $\pm$ 2.1 kPa. Note that the $Threshold_{in}$ is larger than the $Threshold_{out}$ in both configurations.

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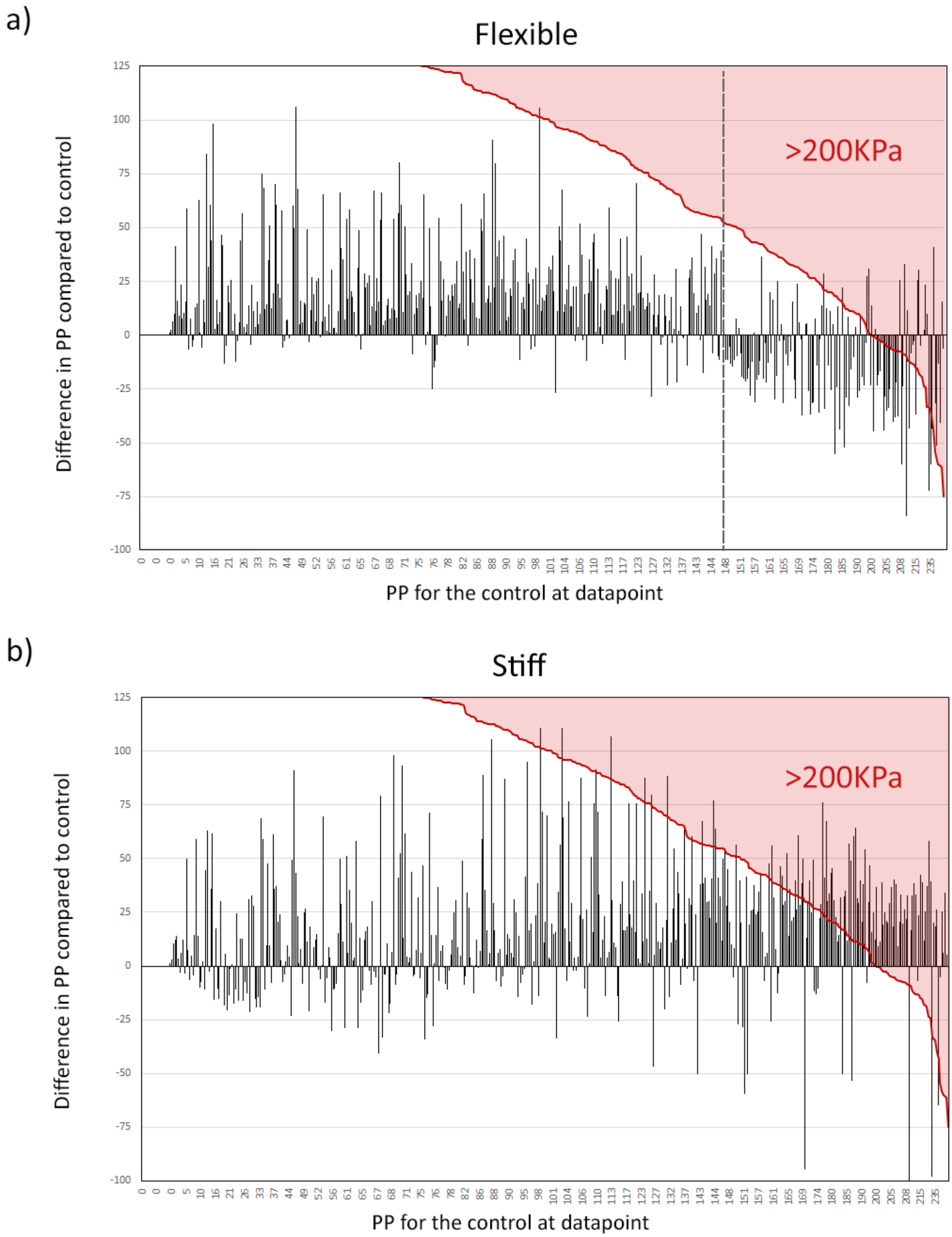

Figure 5.5: *Difference in peak pressures (PP) compared to the control for both the flexible (a) and the stiff (b) insole configuration. All data points are first sorted by the control and then (in cases of multiple data points with the same value for PP in the control condition) the insole. The red area indicates PP at risk for ulcerations (PP > 200 kPa). This area was calculated as all pressures over 200 kPa minus PP found in the control.*

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Sorting the PP data from the in-shoe pressure measurements showed that the $Threshold_{in}$ of the flexible insole was approximately 148 kPa during walking (as this was the point from where most PP were below the control condition), which is comparable to the 144 kPa determined mechanically. As hypothesized, the PP below the threshold found was significantly higher for the flexible insole compared to the control, while PP above the threshold was significantly decreased.

From the in-shoe pressure data it was not possible to determine from what PP the stiff insole configuration resulted in offloading, as PP was mostly larger compared to the control. This is likely due to the fact that the $Threshold_{in}$ was hardly reached while walking with the stiff insole. This threshold was mechanically determined at 253 kPa while the maximal pressure found in the control condition was 275 kPa.

As hypothesized, the number of locations with pressures over 200 kPa was significantly reduced with the flexible insole configuration ($Threshold_{in}$ below 200 kPa). However, while the largest PP was decreased in most cases it was not significantly smaller for the flexible insole configuration compared to the control configuration. The results presented in table 5.1 suggest that the flexible insole can successfully offload PP up to 210 kPa in the control to below 200 kPa, while higher PP remain too high or even increase. Therefore, it seems that the flexible insole has an effective offloading range of 148 – 210 kPa, where in theory PP can be reduced to as low as 59 kPa ($Threshold_{out}$). This limited range is likely due to too many elements dropping down, resulting in insufficient redistribution possibilities across neighboring elements at the locations where PP is over 200 kPa. Another possible unwanted effect of too many elements dropping down is a decrease in stability, as a large supporting area of the insole drops down.

Because of the working mechanism of the self-adjusting insole, which allows PP to increase up to $Threshold_{in}$ in order to offload an area at risk, $Threshold_{in}$ should be below 200 kPa to effectively reduce PP to below 200 kPa. As expected, the stiff insole configuration, which had a $Threshold_{in}$ of 253 kPa, showed a significant increase in the number of sensors over 200 kPa as well as the largest PP compared to the control.

As the $Threshold_{in}$ of the stiff insole configuration is over 200 kPa it is considered too high. The results for the flexible insole configuration also suggest

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that a *Threshold*$_{in}$ of 144 kPa is too low. Therefore, we propose a *Threshold*$_{in}$ of approximately 190 kPa. This will result in less elements dropping down at locations where PP are not considered a risk for ulcerations. As elements only drop down at specific areas that are considered at risk, neighboring elements can support surrounding areas of the foot for a more effective redistribution of PP. Considering the results found for the flexible insole configuration, this potentially increases the effective offloading range to 190 – 250 kPa (or even higher as a result of more specific offloading). Also, the chance of negatively affecting stability will be reduced as the changes in the insole surface are only very locally.

While the self-adjusting insole shows great potential in reducing PP to below 200 kPa, relative reduction in PP is not as large as found in previous studies where footwear was optimized or customized for specific regions of interest where reductions up to 37% were found[18-20]. However, the aim of the self-adjusting insole concept is not to create a large relative reduction in PP at a certain region of interest, but to redistribute all PP over 200 kPa to elements where PP is lower.

Besides the fact that *Threshold*$_{in}$ needs to be optimized, there are some other limitations to the current design of the self-adjusting insole. The first limitation is the use of partial elements near the edge, which are a result of the shape of the insole. These partial elements do not function as intended but mainly fold away. This contributed to the increase in PP at the locations of these partial element, especially at the medial side of the forefoot and first toe. A possible improvement of the current design would be to make the elements smaller, while still allowing the same vertical displacement. This would not only increase the functionality at the edges of the insole, but might also allow for offloading of smaller areas with high pressures. The main limitation to this study is the fact that only young and healthy adults were included. Therefore, the results cannot be directly generalized to patients with diabetes mellitus, especially those that are at high risk of developing DFUs as pressures are mostly higher in these patients and elevated PP are found in a smaller plantar area[21]. To what extend this influences the working of the self-adjusting insole should be further examined in future clinical studies.

Conclusion

This is the first study that showed the functionality of a new self-adjusting insole. With the flexible insole configuration it was possible to significantly reduce the number of sensors that showed peak pressures over 200 kPa in the control configuration. Although there were still peak pressures found over 200 kPa, which was likely the result of the threshold for the flexible insole configuration being too low, the self-adjusting insole shows great potential in reducing peak pressures at the plantar surface of the foot.

Acknowledgements

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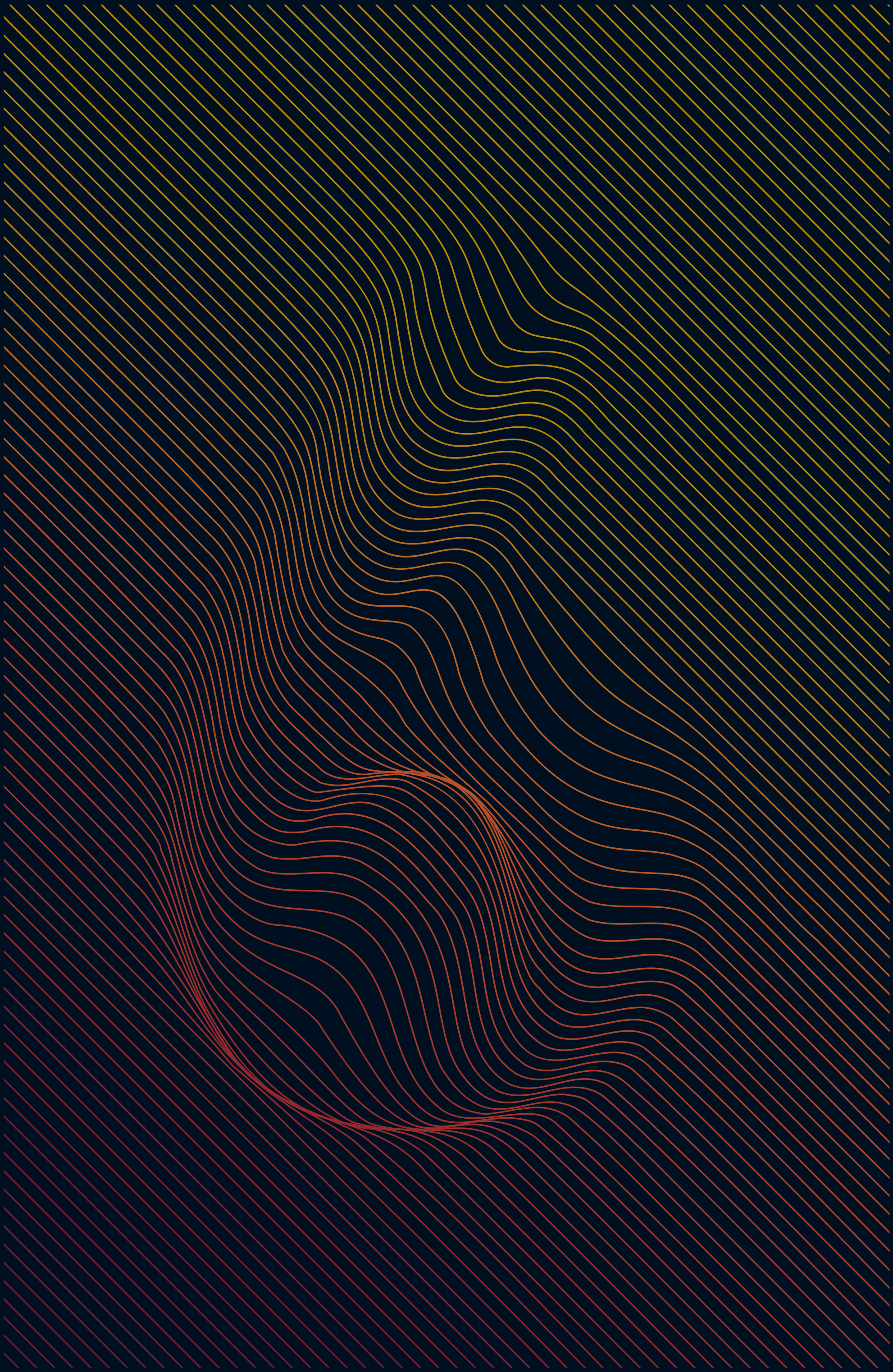

REDUCING IN-SHOE PRESSURE BY A SELF-ADJUSTING INSOLE AND AN ADJUSTABLE ROCKER PROFILE TO BENEFIT PATIENTS DIABETIC SENSORY NEUROPATHY

Abstract

Custom-made insoles and rocker profiles that reduce peak pressures (PP) are commonly prescribed to prevent diabetic foot ulcers (DFU). The design of this footwear is based on empirical knowledge and sometimes pressure measurements. However, pressure spots can change position over time, resulting in insufficient offloading. Therefore, an adjustable rocker profile that allows for quick changes in the rocker shape and a self-adjusting insole that ensures offloading even when pressure spots change position, were designed. The effects of both concepts, used separately and combined, on in-shoe plantar pressure at a region of interest (ROI) were evaluated. The ROI was specified as the area within the forefoot and first toe with the largest PP in the control condition. PP at ROI was significantly reduced in the insole (210 kPa, $p = 0.010$), rocker (170 kPa, $p < 0.001$), and combination (165 kPa, $p < 0.001$) compared to the control (221 kPa). Both the rocker and the combination resulted in significantly lower PP ($p < 0.001$) than the self-adjusting insole, while no difference between the two was found. Although on a group level the rocker alone reduced PP to below the clinical pressure threshold of 200 kPa, some individuals needed the addition of the insole to establish pressures that are considered safe. The current study also showed that when adjusting footwear based on a specific ROI, dangerous PP can occur in other areas that are considered to be at risk . Therefore, it is recommended to not only focus on a small ROI but to consider the entire area at risk of ulcerations.

R. Reints, J.M. Hijmans, K. Postema, G.J. Verkerke

Introduction

Up to 25% of people with diabetes will develop diabetic foot ulcers (DFU) [1]. Especially those who have developed peripheral neuropathy are considered to be at high risk of developing DFU because of a lack of protective feedback[2,3]. DFU tend to be difficult to heal and can eventually lead to lower limb amputation[4,5]. Therefore, it is of the upmost importance that preventive measures are taken.

Elevated peak pressures (PP) at the plantar surface of the foot are considered to be a major contributor to the development of DFU[6,7]. Therefore, preventive guidelines instruct to reduce PP to below 200 kPa [8], or when this is not possible with at least 30%[9]. Custom-made insoles and shoes with rocker profiles are often prescribed to achieve these reductions[10]. Rocker profiles and insoles are made mainly based on empirical knowledge, resulting in great diversity in offloading effects. Also, as a result of changing foot structures[11,12], the location of dangerous PP can change over time, which may deteriorate the originally proper offloading effects.

To overcome these problems two new concepts, an adjustable rocker profile and a self-adjusting insole, were designed at the department of Rehabilitation Medicine of the University Medical Center Groningen, The Netherlands. The adjustable rocker allows for a change in the rocker shape without the need of an orthopaedic workshop. Optimizing the rocker shape on an individual basis could result in better offloading of different areas of the plantar surface of the foot, where pressure spots are located. When these spots change over time the adjustable rocker can be adjusted to optimize the offloading characteristics. The second concept is a self-adjusting insole, which is made out of elements with a supporting surface of 1.25 cm^2 that drops down when a certain pressure threshold is exceeded, while it provides a stable support when pressures stay below the threshold. As a result, the insole surface is lowered only at locations where pressure is too high, resulting in immediate offloading of these particular locations by redistribution of pressure to neighbouring elements that did not drop down. This mechanism might be beneficial for tactile feedback, and with that for stability, compared to soft foam materials currently used in pressure reducing insoles[13,14]. The self-adjusting insole consist entirely out of these elements to ensure proper offloading even when pressure spots change over time.

The aim of the current study was to evaluate the effects on in-shoe PP for both concepts separately and combined by offloading a region of interest (ROI) within the area that is considered at risk for ulcerations (forefoot and first toe) [6,15]. ROI was defined as the region with the highest PP in the control condition.

We hypothesized that the adjustable rocker, the self-adjusting insole, and the combination of both will result in lower PP compared to the control. Also, the combination of both is expected to result in lower PP compared to using both concepts separately.

Methods

Participants

Fifteen healthy male adults participated in this study. Inclusion criteria were adult males (aged 18 years and over) who fitted the adjustable rocker prototype, which was made using a size EU42.5 shoe (Chris, Dr Comfort, Mequon, WI, USA). Exclusion criteria were self-reported injuries, foot deformities, or pathologies that can influence gait, and the daily use of custom-made insoles. Before starting the experiments all participants provided written consent. The Medical Ethics Committee from the University Medical Center, Groningen determined that conduct of this study was not subject to the Medical Research involving Human Subject act (METc 2017/603).

Adjustable rocker profile

Rocker profiles are commonly prescribed for people with diabetes. A rocker profile is an external shoe modification that is characterized by its roll-over shape. Two design parameters that describe the roll over shape of a rocker profile influence the pressure reducing effects[16,17]. The first design parameter is the point where the rocker starts on the longitudinal axis, known as the apex position. The other design parameter is the apex angle, which is the angle between the longitudinal axis and the rocker axis [16-18]. Both design parameters are shown in figure 6.1.

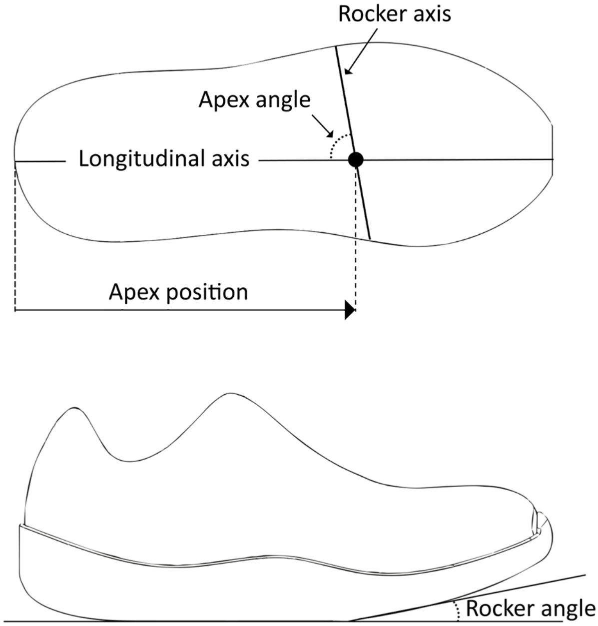

Figure 6.1: *Rocker design parameters. Apex position: location where the rocker axis intersects with the longitudinal axis. Apex angle: the angle between the rocker axis and the longitudinal axis.*

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With the adjustable rocker profile it is possible to adjust both the apex position and apex angle, see figure 6.2. This is achieved by two knobs that each slide across a rail which is placed between the inner sole and original outer sole which was cut from the shoe (Chris, size 42.5EU, Dr Comfort, Mequon, WI, USA). The two rails and sliders are aligned parallel to the longitudinal axis of the shoe. One rail is positioned medial to the longitudinal axis, the other lateral. The rails are integrated in the carbon reinforcement that is used to stiffen the outer sole. The imaginary line that goes through the middle of both knobs defines the rocker axis. Each knob is fixed to the slider with a bolt. By loosening this bolt the position of the knob can be changed across the rail, this way the apex position and/or apex angle can be adapted. In this prototype, a Velcro strap was used to fixate the original outer sole to the upper at the toes. This allowed for easy access to the knobs. A layer of 3 mm Polyethylene (Streifylast, Streifeneder, Emmering, Germany) was placed between the knobs and the original outer sole to prevent the knobs from digging into the original outer sole material. To accommodate for the increase in height by the knobs and the Polyethylene, a layer of Ethylene-vinyl acetate (EVA, 70 durometer, shore A) was positioned at the heel between the carbon reinforcement and the original sole. The height of the adjustable rocker profile shoe was increased by 23 mm compared to the original shoe.

Apex settings

The apex settings were based on the location of the first and fifth metatarsal head (MTH1 and MTH5) in each individual. Through palpation the location of MTH1 was determined and marked on the shoe at the medial side of the shoe. The same was done at the lateral side of the shoe for MTH5, these marks were connected with a line referred to as the 0% line. At a distance of 5% of the total shoe length proximal to the 0% line another reference line was drawn, referred to as the 5% line. Three apex settings were tested; Setting 1: both knobs at 0% line, Setting 2: medial knob at 5%, lateral knob at 0%, Setting 3: medial knob at 0%, lateral knob at 5%.

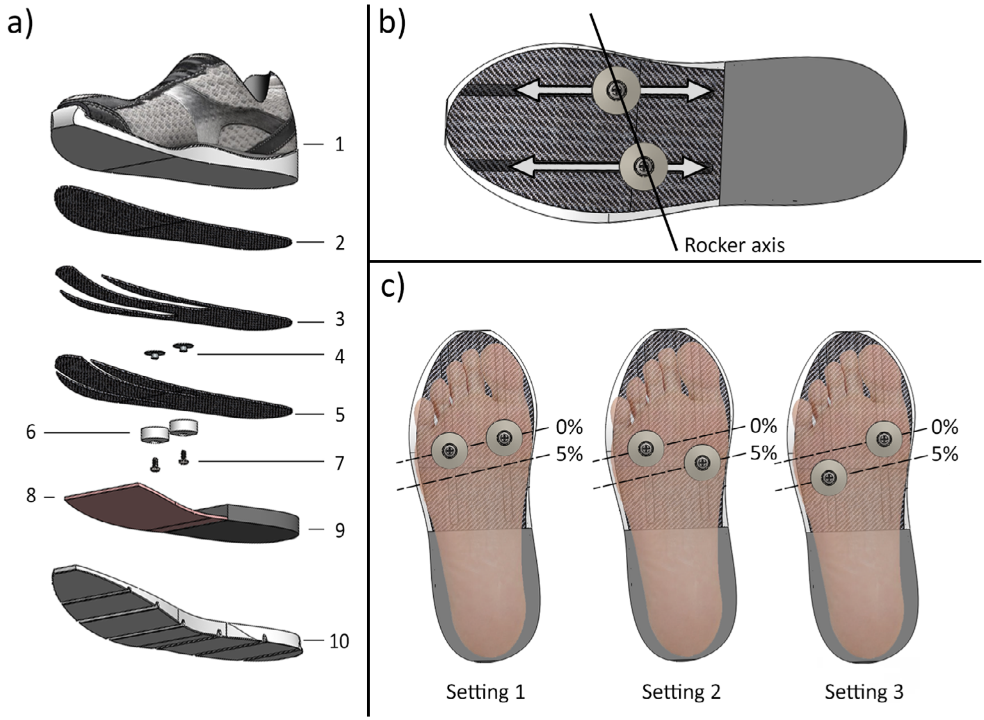

Figure 6.2: *Representation of the adjustable rocker profile. a) Exploded view of the adjustable rocker profile assembly (1: upper of the Dr Comfort Chris shoe, 2: top carbon layer, 3: middle carbon layer, 4: tee-nut, 5: bottom carbon layer 6: 3D-printed knobs, 7: bolts, 8: Polyethylene plate, 9: added EVA at the heel, 10: Original outer sole of the Dr Comfort Chris shoe). B) Movement possibilities of knobs across rails. C) Used settings in this study.*

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Self-adjusting insole

The self-adjusting insole consists entirely of hexagonal shaped elements that collapse when a pressure over a certain threshold ($Threshold_{in}$) is applied. When the element collapses, the supporting surface of the element drops down approximately 3 mm, which results in a lowering of the plantar pressure at the location of that element by pressure redistribution across neighbouring elements. When the pressure is subsequently reduced considerably (for example during swing phase) the insole is restored to its original shape. Two insole configurations were used, a flexible ($Threshold_{in}$ around 148 kPa when using Pedar-X) and a stiff ($Threshold_{in}$ around 274 kPa when using Pedar-X) version. The height of the insoles was 9 mm. The other dimensions were based on the shoes in which the insoles were tested (Chris size 42.5 EU, Dr Comfort, Mequon, WI, USA). Each self-adjusting insole consisted of 105 hexagonal shaped elements, across the entire insole surface, each element with a supporting surface of 1.46 cm^2 (figure 6.3). The insoles were 3D-printed by a fused deposition modelling (FDM) printer using a flexible filament (Ninjaflex, Thermoplastic Polyurethane, 85 durometers shore A).

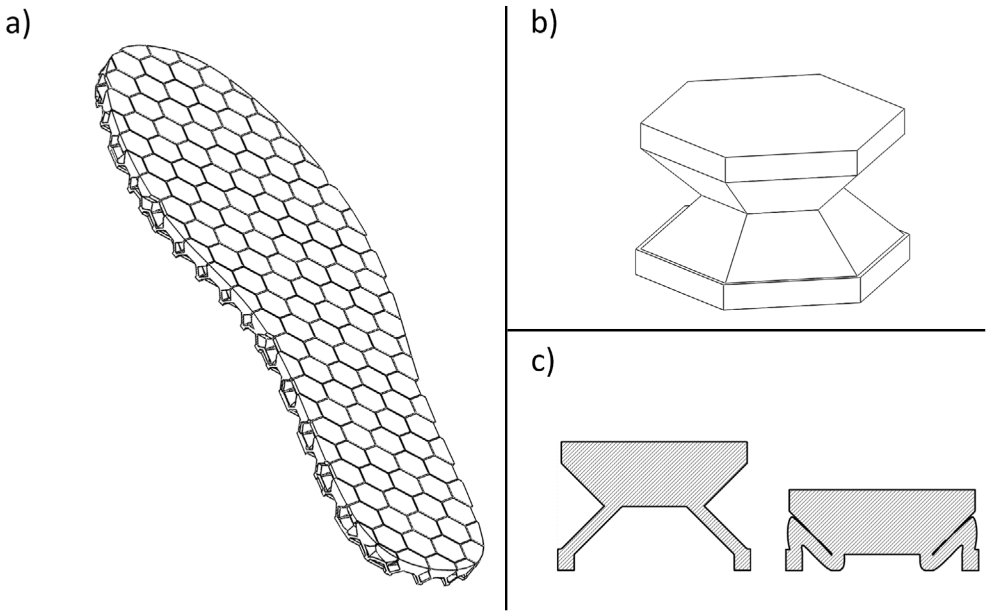

Figure 6.3: *The self-adjusting insole (a) which consists of 105 hexagonal shaped elements (b). The elements buckle when pressures exceed a certain threshold (c).*

In-shoe pressure measurements

The Pedar-X® system (Novel, Munich Germany; sampling frequency 100 Hz) was used to measure in-shoe pressures. The insoles were calibrated as recommended by the manufacturer and zeroed between conditions with exception of the adjustable rocker settings as the shoes did not need doffing and donning to change settings.

Experimental procedures

All measurements were performed at the Motion lab of the Department of Rehabilitation Medicine, University Medical Center Groningen. First age, height, bodyweight, and dominant leg were determined. During the experiments participants wore seamless socks (Ankle socks, Dr. Comfort, Mequon, WI, USA). A total of seven conditions were measured; one control, two insole conditions, three rocker conditions, and a combination of the insole and rocker with the lowest PP at a region of interest (ROI). Per condition, participants were asked to walk ten times across the Motion Lab for accommodation before the measurement started, after which five trials were recorded.

Each participant started with a control condition, which was an unmodified pair of Dr Comfort Chris shoes (same as the shoe used in the adjustable rocker profile prototype) with the 6 mm Ethylene vinyl acetate (EVA, 25 durometer, shore A) inlays that came with the shoes, which were elevated by placing 3 mm cork underneath the inlays to get the same height as the self-adjusting insoles. For randomization, the conditions were divided into four blocks; 1) control, 2) rocker settings, 3) insole configurations, and 4) combination. The control block was always measured first as the ROI was determined using the third trial of this condition. Also, the preferred walking speed was determined during this condition using the Speedclock app (Sten Kaiser, v10.4). During following measurements walking speed needed to be within a ± 10% range of the preferred walking speed. The combination block was always measured last, as first the rocker setting and insole configuration with the lowest PP at the ROI needed to be determined using the third trial of each condition. The remaining two blocks were randomized in a balanced way such that either block would be the second block for a minimum of seven times. The same randomization was performed within the insole configuration block. Within the rocker setting block, rocker settings were randomized such that each rocker setting would be the first, second, and third measurement five times.

Data analysis

For each trial three midgait steps of the dominant leg were selected using Pedar-X® Step analysis (Novel; Munich, Germany), the first twelve midgait steps[19] without missing data were selected for further analysis using Matlab (R2016a).

Peak pressures (PP) were calculated for each sensor within the first toe, the medial forefoot, central forefoot, and lateral forefoot (33 sensors) by selecting the highest measured pressure within a step for each of the sensors and calculating the mean across all twelve steps for each participant. For each participant the largest PP for both the ROI (PP_{ROI}) and the entire area at risk (PP_{AAR}) were calculated for the control, combined condition, and the insole and rocker used in the combined condition.

Statistical Analysis

To describe study population characteristics, means and standard deviations were determined for the age, bodyweight, height, and walking speed. PP_{ROI} and PP_{AAR} were analyzed separately with a Linear Mixed Model (Type III testing, diagonal covariance structure) estimating the effects of the control, insole, rocker, and combination. All statistical analyses were performed using SPSS statistics (23.0.0.0). Level of significance was set at $p < 0.05$.

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Results

Determining the region of interest, rocker setting with lowest PP at ROI, and insole configuration with lowest PP at ROI using only the third trial resulted in the wrong combination for three participants, as the mean across twelve steps differed from the three steps during this trial. Data from these three participants were removed from the analysis as it was the intention of this method to study the effects of a personalized combination of the rocker and insole that worked best for each individual. The remaining twelve participants had a mean (±SD) age of 23 (±3.8) years, bodyweight of 76 (±8.2) kg, height of 1.80 (±0.05) m, and walking speed of 1.40 (±0.10) m/s.

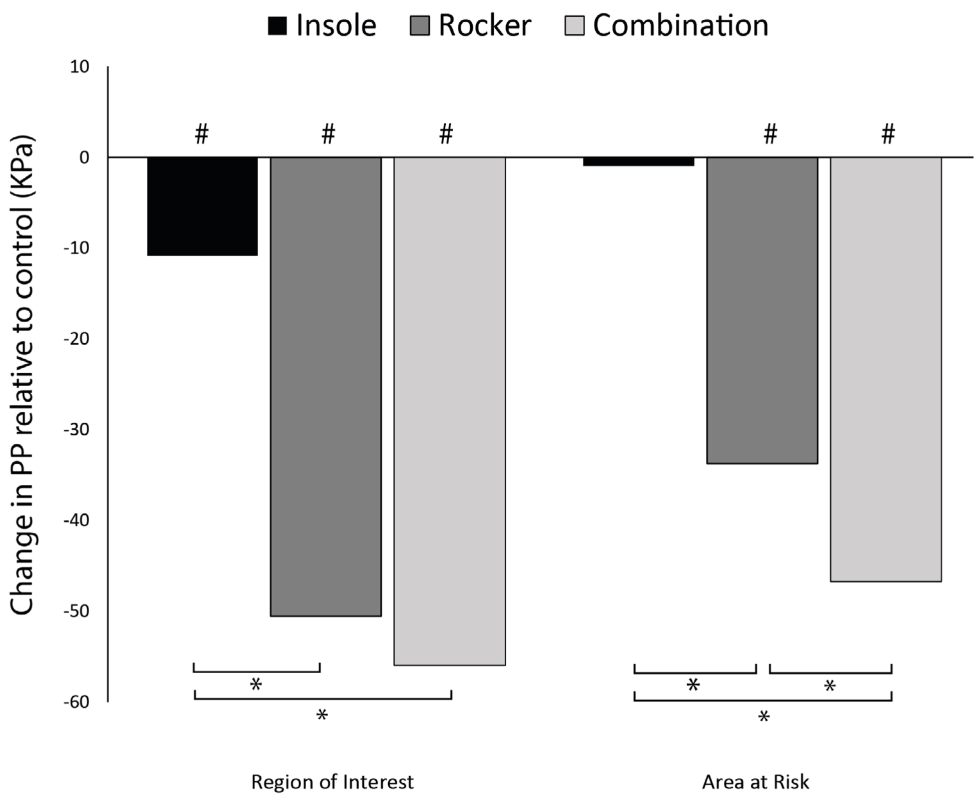

Figure 6.4: *Changes in the largest peak pressure (PP) at the region of interest (ROI) and the entire area at risk, for the insole, rocker, and combination of both compared to the control condition. #: Significant difference compared to control condition (p < 0.05). *: Significant difference between conditions (p < 0.05).*

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Changes in PP are shown in figure 6.4. Mean (95% confidence interval) PP was 221 (215-227) kPa for the control condition for both PP_{ROI} and PP_{AAR}. This value was equal for both outcome measures as ROI was defined by the sensor with the largest PP within the entire area at risk. The use of the self-adjusting insole significant reduced ($p = 0.010$) PP_{ROI} compared to the control to 210 (204-216) kPa. At the area at risk there was no significant reduction. The use of the adjustable rocker profile showed a significant reduction in PP at both the ROI and the area at risk compared to the control and to the self-adjusting insole ($p < 0.001$). PP_{ROI} was reduced to 170 (165-176) kPa, while PP_{AAR} was reduced to 187 (182-193) kPa. With the combination of both the insole and the rocker, PP was significantly reduced compared to the control and the insole at both the ROI and the area at risk ($p < 0.001$). At the area at risk the combination also showed a significant reduction compared to the adjustable rocker (p = 0.001). For the combination PP_{ROI} was 165 (160-171) kPa and PP_{AAR} was 174 (170-179) kPa.

Table 6.1 shows the ROI, the used self-adjusting insole configuration, the used rocker setting, PP_{ROI} and PP_{AAR} for each participant. Also, the number of sensors with PP over 200 kPa are shown for each condition to give insight on the area where PP is considered to be too high.

Table 6.1: *Region of interest, used insole configurations and rocker settings, peak pressures (PP) at region of interest (PP_{ROI}), and peak pressures at area at risk (PP_{AAR}) for each participant in* kPa*. Area represents the number of sensors with PP over 200* kPa*. HAL: Hallux, MFF: Medial forefoot, CFF: Central forefoot.*

Participant	ROI	Insole	Rocker	Control		Insole			Rocker			Combination		
				PP	*Area*	*PP_{ROI}*	*PP_{AAR}*	*Area*	*PP_{ROI}*	*PP_{AAR}*	*Area*	*PP_{ROI}*	*PP_{AAR}*	*Area*
1	CFF	Flexible	Setting 2	218	3	213	230	3	179	179	0	158	171	0
2	HAL	Flexible	Setting 2	209	1	208	208	1	187	187	0	183	183	0
3	CFF	Flexible	Setting 1	206	5	179	179	0	153	159	0	159	159	0
4	MFF	Flexible	Setting 1	234	4	204	248	2	236	236	1	203	203	1
5	CFF	Flexible	Setting 2	260	5	226	243	4	181	181	0	151	151	0
6	MFF	Flexible	Setting 2	205	1	170	176	0	141	186	0	159	171	0
7	HAL	Flexible	Setting 1	258	6	241	249	5	203	203	1	199	199	0
8	CFF	Flexible	Setting 2	175	0	161	189	0	163	211	1	168	168	0
9	MFF	Flexible	Setting 2	254	4	223	223	3	126	152	0	116	129	0
10	MFF	Stiff	Setting 2	208	3	227	228	4	150	225	2	138	173	0
11	HAL	Stiff	Setting 3	244	3	270	270	9	205	205	1	224	224	3
12	CFF	Flexible	Setting 1	209	2	197	197	0	124	133	0	139	173	0

Discussion

The current study showed the effects of an adjustable rocker profile and a self-adjusting insole, separately and combined, on in-shoe plantar pressures. As hypothesized, PP at the ROI was significantly reduced with the self-adjusting insole, the adjustable rocker profile, and the combination of both compared to the control condition. Also, the combination resulted in significantly more reduction of PP compared to the self-adjusting insole. There was no significant difference found between the combination and the adjustable rocker profile for the ROI.

The self-adjusting insole reduced PP significantly with an average of 11 kPa at the ROI. For the entire area that is considered at risk for diabetic foot ulcers no significant reduction was found. This indicates that while PP is offloaded at the ROI higher PP are found elsewhere, which in some individual cases were higher than the initial PP found in the control condition. It is likely that the thresholds of the used self-adjusting insole configurations have contributed to these findings. The flexible configuration had a $Threshold_{in}$ of around 148 kPa, meaning that pressures over 148 kPa will result in dropping down of the elements' supporting surfaces. This may have resulted in too many elements dropping down leaving insufficient possibilities for redistribution. This might explain why PP could not be reduced to below 200 kPa when the largest PP was over 209 kPa (see table 6.1). The stiff configuration had a $Threshold_{in}$ of around 254 kPa, and was used in only two participants. In both cases the insole configuration resulted in an increase of PP compared to the control condition, which can be explained by elements not dropping down at all, as PP in the control condition was below $Threshold_{in}$, resulting in a rigid flat surface while the soft 6 mm EVA (25 durometer, shore A) in the control condition has some pressure redistributing properties. It is expected that a $Threshold_{in}$ of approximately 190 kPa will result in better offloading of PP over 200 kPa to below this critical level, as this will result in less elements dropping down at locations where PP is not considered dangerous while still dropping down at the locations that are considered at risk.

The adjustable rocker profile alone resulted in significant reductions in both the ROI as well as the area at risk resulting in average PP below 200 kPa, which is a clinical threshold that helps to prevent diabetic foot ulcers[8]. Only one participant showed an increase in PP at the ROI compared to the control, while the other eleven showed great reductions up to 128 kPa (or 50%). In two individual cases there was an increase of PP outside of the ROI over 200 kPa and in both cases this was also an increase in PP compared to the control. This shows that when using a rocker profile based on a specific ROI it is very important to consider the possibility that PP can shift to other regions. Together with the fact that even with similar ROIs different settings resulted in the lowest PP between participants, these findings show that the design of rockers require an individualized approach.

The combination of the self-adjusting insole with the adjustable rocker showed the largest reduction in PP compared to the control in both the ROI and the entire area at risk. On group level reductions of 25.3% at the ROI and 21.3% at the entire area at risk were found, while on an individual level reductions as high as 54.3% at the ROI and 49.2% at the area at risk were found. These effects were similar to a study by Bus et al. (2011) where footwear was optimized by a rehabilitation specialist and an orthopeadic shoe technician based on a ROI, which resulted in a reduction of 30.2% on a group level and up to 50% within participants. The footwear modifications in this study were mainly insole modifications or small rocker alterations, as completely new rockers or rocker modifications that need addition of midsole material would require special machinery and cost too much time. This is where the new self-adjusting insole and adjustable rocker profile show their possibilities as the self-adjusting insole would not require modifications, and the adjustable rocker allows making rocker profile modifications that would normally cost much time and special machinery within seconds using only a screwdriver.

The combination also showed a significant reduction compared to the self-adjusting insole for both the ROI and area at risk. While for the ROI PP was not significantly more reduced compared to the adjustable rocker profile, PP was significantly lower when considering the entire area at risk. Although the group effects indicate that the rocker alone might be sufficient to reduce PP to below 200 kPa, individual results show that sometimes the combination might be needed to get the desired reduction.

It is important to note that postural stability could be negatively affected by rocker shoes and insoles that are used to reduce PP[20,21]. Especially in people who have developed neuropathy as a result of diabetes this may become more of a problem, as their tactile sensation is already decreased. In rocker profiles the base of support decreases when the apex is positioned more proximal compared to normal walking shoes. Previous studies with healthy subjects showed that these rocker profiles negatively affected postural stability[21,22]. While the apex positioning in the current study was not as proximally as in the rockers measured in previous studies, the effect of the adjustable rocker on stability should be further examined, especially when the apex is positioned more proximal or when the apex angle is changed more drastically. In insoles a compliant material that changes along with the foot at any time like gels or other highly resilient materials might seem promising for redistribution of PP, they negatively affect stability, balance, and tactile sensation from the plantar surface of the foot[20,23]. Because of the self-adjusting insole's working mechanism, that only allows small local changes of the insole surface at the locations where PP is too high, we expect that stability will not be negatively affected. However, this should be examined in future research.

A limitation of the current study was the method to determine ROI, the insole configuration, and the rocker setting used to determine the combination condition, as this was based solely on PP measured during the third trial of each condition. The mean PP across twelve steps sometimes differed from the PP found in this one trial of three steps. Another limitation is the study population. As the study was performed in healthy young men, it affects the generalizability to people with diabetes.

Conclusion

Both the combination and the adjustable rocker profile alone significantly reduced PP to below 200 kPa at the ROI when compared to the control shoe, with mean reductions of 51 kPa and 56 kPa, respectively. PP were not significantly reduced in the combination compared to the adjustable rocker profile at the ROI. However, in some individual cases it ensured PP to be below 200 kPa. The self-adjusting insole alone did result in significant reductions of PP at the ROI but PP was not reduced to below 200 kPa and sometimes increased PP at other areas at risk. This was likely due to the used insole configurations as $Threshold_{in}$ was considered too low for the flexible configuration and too high for the hard configuration. It is expected that PP over 200 kPa are offloaded better when the $Threshold_{in}$ is approximately 190 kPa. The current study also showed that when adjusting footwear based on a specific ROI, dangerous PP can occur in other areas that are considered to be at risk. Therefore, it is recommended to not only focus on a small ROI but to consider the entire area at risk of ulcerations being the first toe and the forefoot. Finally, the results of the currents study seem promising when it comes to offloading the plantar surface of the foot and warrants further development of both the self-adjusting insole and the adjustable rocker profile.

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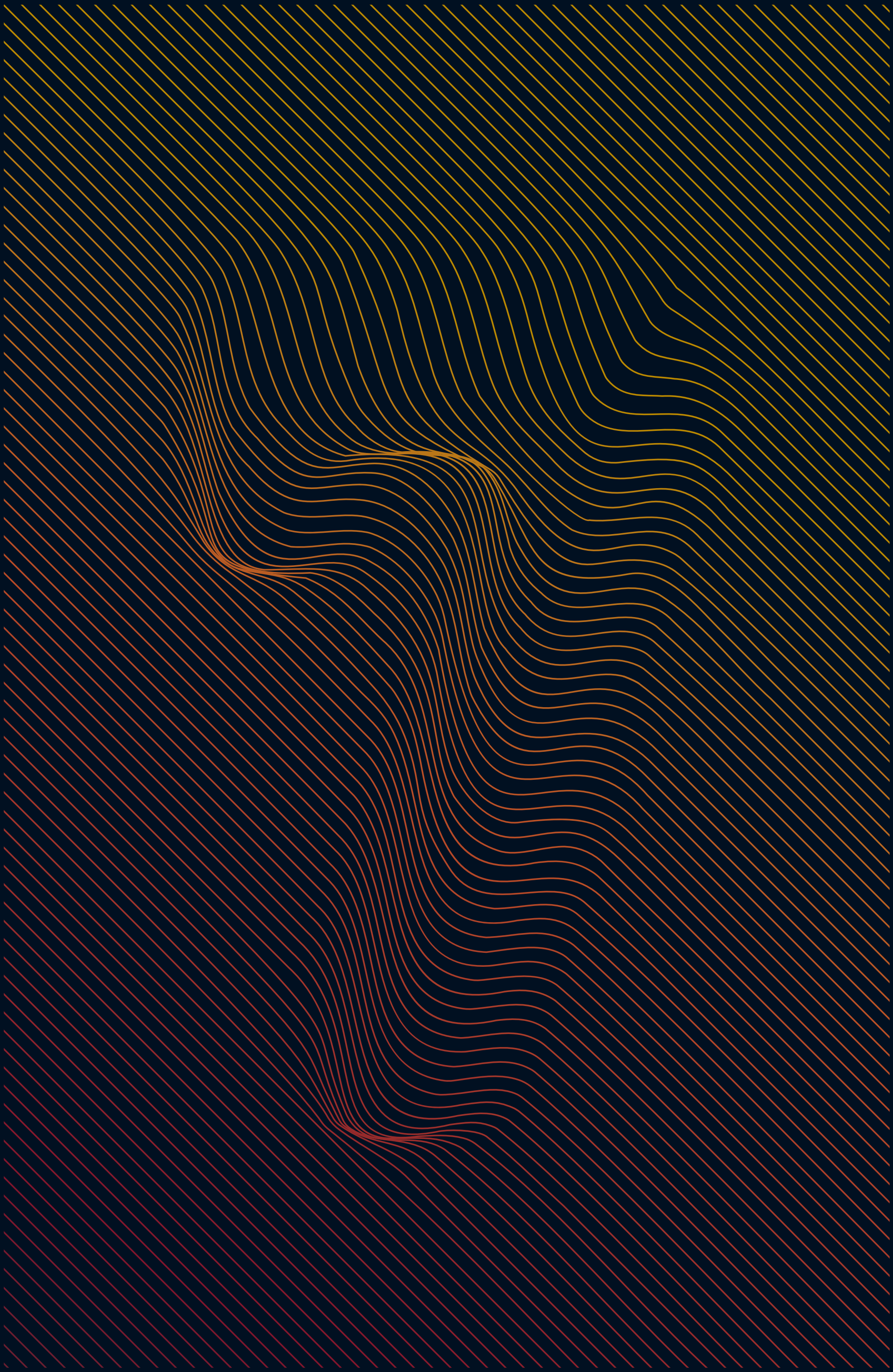

REDUCING PLANTAR PEAK PRESSURES IN DIABETIC PATIENTS WITH SENSORY NEUROPATHY BY COMBINING A SELF-ADJUSTING INSOLE AND AN ADJUSTABLE ROCKER PROFILE

Abstract

Rocker profile shoes and custom-made insoles are often prescribed to prevent diabetic foot ulcers (DFU) by reducing elevated peak pressures (PP). In daily practice the design of this footwear is mainly based on empirical knowledge, resulting in great variability in offloading effects. Also, over time changes in foot structures can result in a relocation of the PP that are considered dangerous, causing ineffective offloading by the footwear. Therefore, an adjustable rocker profile that allows for quick changes in the rocker shape and a self-adjusting insole that ensures offloading even when pressure spots change position, were designed. The effects of both concepts, used separately and combined, on in-shoe plantar pressure were evaluated in four patients with diabetes and neuropathy. Also, spatiotemporal parameters and perceived comfort were evaluated. All four participants had initial PP over 200 kPa (up to 293 kPa), which could be reduced to below 200 kPa when combining the adjustable rocker profile and the self-adjusting insole. When used separately this was only achieved with the adjustable rocker profile in one patient. No relevant changes in spatiotemporal parameters were found. The adjustable rocker profile scored low on perceived comfort in two patients, which was improved when combined with the self-adjusting insole. This was the first study evaluating the adjustable rocker profile and self-adjusting insole in diabetics with neuropathy. The results in the current study are promising however, a larger clinical trial with more participants is needed to validate the current results.

R. Reints, J.H. Hijmans, K. Postema, G.J. Verkerke

Introduction

Currently over 451 million adults have diabetes[1,2]. Between 19% and 34% of these adults develop diabetic foot ulcers (DFU[3-5]. More than 50% of DFU get infected, and approximately 20% of infected DFU will result in amputation of the affected limb[3,4,6]. Mortality at five years after diabetes related amputations is reported up to 80%[4,5]. Peripheral neuropathy is considered to be the largest contributor to DFU development, as the neuropathy leads to reduced till no protective feedback[7]. Elevated peak pressures (PP) result in callus- and small wound formation, often all remaining unnoticed until it is too late[7].

Rocker profile shoes and custom-made insoles are often prescribed to prevent DFU by reducing the elevated PP to below 200 kPa [8] or by at least 30%[9]. Rocker profile shoes that are used to lower PP commonly have a rocker axis, or fulcrum, placed proximal to the metatarsal heads (MTHs) allowing for an early rollover. The location and orientation of the rocker axis are described by rocker design parameters referred to as the apex position and the apex angle (figure 7.1). Different apex positions and apex angles can result in offloading of different areas of the plantar surface of the foot. [10,11]

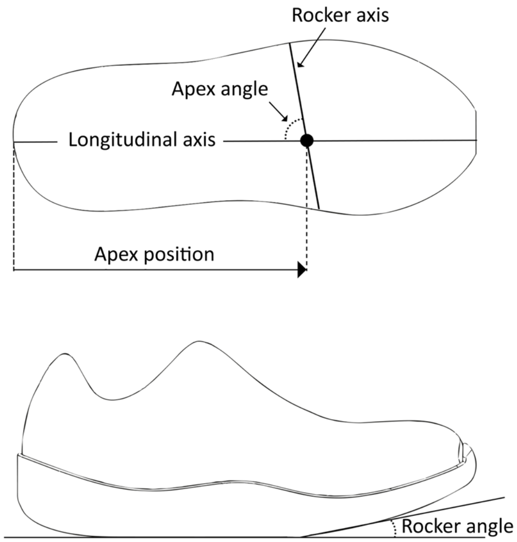

Figure 7.1: *Rocker design parameters. Apex position: location where the rocker axis intersects with the longitudinal axis, noted as percentage of total shoe length measured across the longitudinal axis. Apex angle: the angle between the rocker axis and the longitudinal axis.*

In custom-made insoles pressures are reduced by using harder materials for the supporting base of the insole, while softer materials are used to allow for dampening and pressure distribution at high pressure spots.

However, guidelines for orthopaedic footwear are not well standardized[12]. In daily practice the design of rocker profile shoes and custom-made insoles is mainly based on experience of the orthopaedic shoe technicians, resulting in great variability in offloading effects. Also, changes in foot structures that occur over time in people with diabetes can result in a relocation of the PP that are considered dangerous, causing ineffective offloading by the footwear and an increase of the risk for DFU.

Two new concepts were designed at the Department of Rehabilitation Medicine of the University Medical Center Groningen, The Netherlands to overcome the beforementioned problems. The first concept is an adjustable rocker profile, that allows for adjustments of the apex position and/or apex angle, without the need of an orthopaedic workshop. As adjustments only take a few seconds, better individualization is possible and when the location of elevated PP changes, the apex position and/or angle can be adjusted to accommodate these changes. The second concept is a self-adjusting insole, which consist entirely out of small elements. These elements drop down when pressures on it exceed a set threshold, which lowers the insole surface at the location of that element. This results in immediate offloading at these locations as pressures are redistributed over neighbouring elements that did not collapse. When pressure is lowered substantially the elements return to their original shape again. As the insole surface is flat and remains rigid up to the threshold this might also be beneficial for tactile feedback, and with that for stability, compared to currently used pressure reducing insoles[13-15].

The aim of the current case series was to explore the offloading effects of both concepts separately and combined at the forefoot and first toe of patients with diabetic neuropathy. Secondary, effects on spatio-temporal parameters and perceived comfort were explored. We hypothesized that combining both concepts will be most effective in reducing PP.

Methods

Participants

Four ambulatory adults with diabetes, peripheral neuropathy, and shoe sizes between 36EU and 45EU where included in this study. To determine neuropathy sensibility was tested using a 10 gr monofilament at the first toe, MTH1, MTH5, and heel of which at least two locations needed to test insensible. Exclusion criteria were current or recent (<2 month ago) ulcerations, extreme foot deformities like Charcot-feet that do not allow participants to fit ready-to-wear shoes, the use of walking aids (with exception of the use of insoles). Participants provided written consent before the start of the experiments. This case series is part of a larger study of which the Medical Ethics Committee from the University Medical Center, Groningen approved the conduct (METc 2018/240).

Adjustable rocker profile

The adjustable rocker profile allows for changes in the apex position and apex angle, as seen in figure 7.2. This is achieved by two knobs that slide across two rails that are integrated in to the carbon reinforcement of the shoe parallel to its longitudinal axis. One rail is placed medial to the longitudinal axis, the other lateral. By loosening a bolt in the middle of the knobs each knob can be moved across the rails. By tightening the bolt, the knob can be secured at the desired position. The rocker axis is identified by an imaginary straight line that intersects with the middle of both knobs.

Three apex settings, all based on the location of the first and fifth metatarsal head (MTH1 and MTH5) in each individual, were used in this study. The location of MTH1 and MTH5 were determined through palpation and marked on the side of the shoe. The line connecting these marks is referred to as the 0% line. Another reference line, referred to as the 5% line, was drawn proximal to the 0% line at a distance of 5% of the total shoe. The three used apex settings were; Setting 1: both knobs at 0% line, Setting 2: medial knob at 5%, lateral knob at 0%, Setting 3: medial knob at 0%, lateral knob at 5%. One apex setting was used for each individual, based on the location of the largest PP. Based on the results in healthy participants Setting 1 was used for PP at the first toe, Setting 2 was used for PP at MTH1-4, and Setting 3 was used for PP at MTH5.

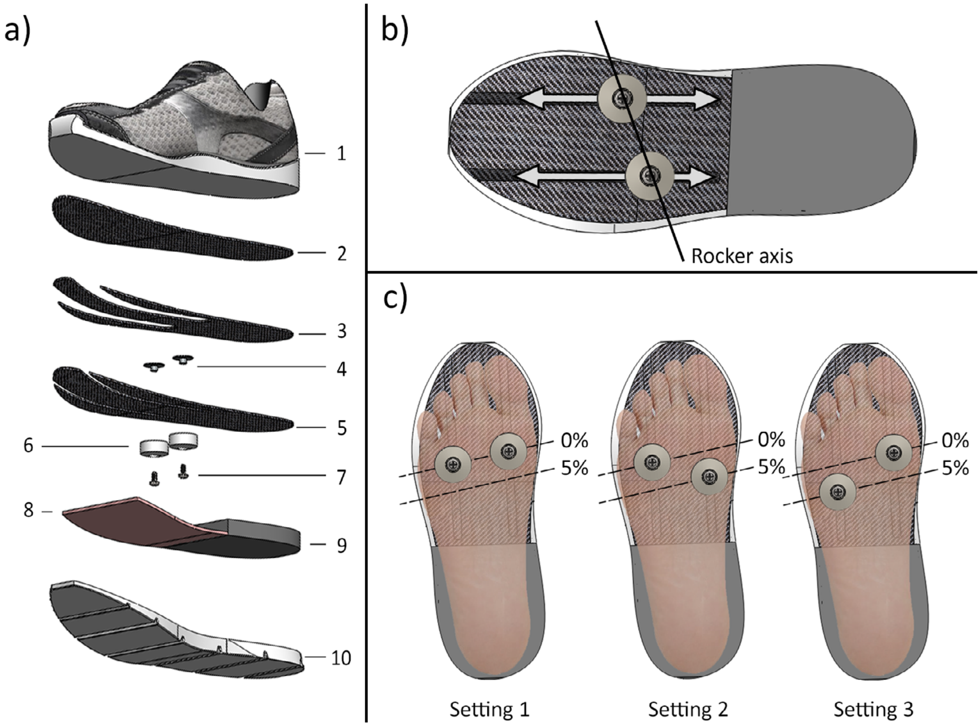

Figure 7.2: *The adjustable rocker profile. a) Exploded view of the adjustable rocker profile assembly (1: Dr Comfort Chris shoe without outer sole, 2: top carbon layer, 3: middle carbon layer, 4: tee-nut, 5: bottom carbon layer 6: 3D-printed knobs, 7: bolts, 8: Polyethylene plate, 9: added EVA at the heel, 10: Original outer sole of the Dr Comfort Chris shoe). B) Movement possibilities of knobs across rails. C) Possible settings in the current study.*

Self-adjusting insole

The self-adjusting insole (figure 7.3) consists entirely of hexagonal shaped elements that only drop down when pressures exceed 190 kPa, resulting in a lowering of the insole surface of approximately 3mm at the location of the element. This lowering results in reduction of the plantar pressure at the location of that element as pressures are redistributed across neighbouring elements that did not drop down. The insole surface returns to its original shape when subsequent pressures are substantially lower, which is likely during the swing phase of gait. The height of each self-adjusting insole was 9 mm. The outline of the insoles were based on the shoes in which the insoles were tested (Size 36-40EU: Meghan, size 41-45 EU: Chris, Dr Comfort, Mequon, WI, USA).

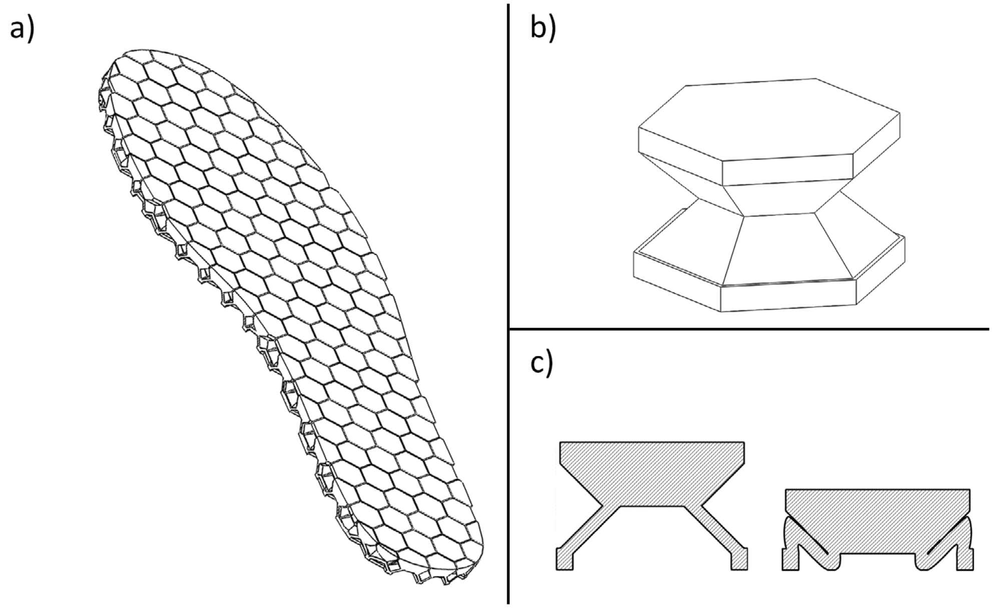

__Figure 7.3:__ The self-adjusting insole (a) which consists entirely of hexagonal shaped elements (b). The elements buckle when pressures exceed a certain threshold (c).

In-shoe pressure measurements

In-shoe plantar pressure was measured using the Pedar-X® system (Novel, Munich Germany; sampling frequency 100 Hz). The insoles were calibrated as recommended by the manufacturer and zeroed before each condition.

Spatiotemporal parameter measurements

A ten camera Vicon system with a custom made fourteen marker setup was used for the spatiotemporal measurements. Although fourteen markers were placed (two markers on the lower back, two markers just above the anterior superior iliac spine, all attached to the Pedar-X strap. A marker was placed at both upper and lower legs. Three markers were placed on each shoe; one at the heel, one the medial side and one on the lateral side of the nose of the shoe) only the heel and the lower back markers were used to determine spatiotemporal parameters. The markers on the lower back were used to determine walking speed during each trial. The heel markers were used to determine the stride length, stride width, and stride time. One static calibration was performed before the first condition by positioning the participant in the middle of the lab with arms wide and knees slightly bend.

Experimental procedures

The experiments were performed at the Motion lab of the Department of Rehabilitation Medicine, University Medical Center Groningen. First age, height, bodyweight, type of diabetes, ulcer history, and shoe size were determined. The participants were equipped with the Pedar-X system and the markers. A total of four conditions was measured. Starting each condition participants walked across the 10 m motion lab five times for accommodation after which four walks across the motion lab, further referred to as trials, were recorded. After each condition the participants scored shoe comfort by placing a vertical line on a 100mm Visual Analog Scale (VAS) of which the outmost left (0mm) was labelled “very uncomfortable” and the outmost right (100mm) was labelled “very comfortable” [16,17].

The first condition in all four participants was the control, which consisted of an unmodified pair of the same dr Comfort shoes used in the adjustable rocker prototype with a 6 mm EVA insert (Shore 25A) on top of 3 mm cork to get the same height as the self-adjusting insole. The preferred walking speed was determined as the mean walking speed during this condition, while the participants were asked to walk at a comfortable speed. The walking speed during following conditions needed to be within a range of ±5% of the preferred walking speed. Also, the location with the largest PP was determined. This could be the first toe, MTH1, MTH2-4, or MTH5, as these are considered to be the areas that are at greatest risk for ulcer development as a result of PP[18-20]. The order of the following three conditions being the adjustable rocker profile, self-adjusting insole and the combination of both were randomized.

Data analysis

Plantar pressure data for the foot with the most insensible locations (based on the monofilament measurement) was used for further analysis. In case of equal number of insensible locations the preferred leg, which was determined by asking the participant with what leg the participant would kick a ball, was used. Three midgait steps of all four trials were selected using the Step Analysis software (Novel Gmbh, Munich, Germany), resulting in a total of twelve midgait steps for analysis[21]. PP was calculated for every sensor distally from the midfoot by determining the largest PP for each step and calculating the mean across all twelve steps. For spatiotemporal parameter calculation only data from the middle four meters were included.

Results

Participants

A total of four adults (three male and one female) with diabetes mellitus and neuropathy were included in the current case series. Participant characteristics and the rocker setting that was used during the experiments are described for each participant in table 7.1.

Table 7.1: *Characteristics and the rocker setting used for each participant. Monofilament reading shows at how many locations the 10 gr monofilament was sensed.*

Participant	Sex	Age (years)	Bodyweight (kg)	Heigth (m)	Shoesize (EU)	Diabetes	Since	Monofilament reading Left	Monofilament reading Right	Walking speed (m/s)	Rocker setting
1	Male	61	106,5	1,83	45	Type II	2014	0/4	2/4	1,38	2
2	Male	72	113	1,82	45	Type II	2008	1/4	0/4	0,94	1
3	Female	51	96,4	1,57	39	Type II	1994	0/4	3/4	1,03	2
4	Male	70	95,7	1,79	45	Type II	2011	2/4	0/4	0,95	1

In-shoe peak pressures

The combination of the adjustable rocker profile and the self-adjusting insole resulted in the largest reductions ranging from 44 kPa to 123 kPa, and resulted in a decrease of PP till below 200 kPa in all four participants. The rocker profile resulted in the second largest PP reductions, ranging from 26 kPa to 64 kPa. In one participant the rocker alone ensured PP below 200 kPa. The self-adjusting insole resulted in the least reduction of the largest PP. Reductions ranged from 13 kPa to 26 kPa, and in one participant the largest PP was increased by 4 kPa. Pressure maps showing PP in the forefoot and toes for all conditions are shown in figure 7.4.

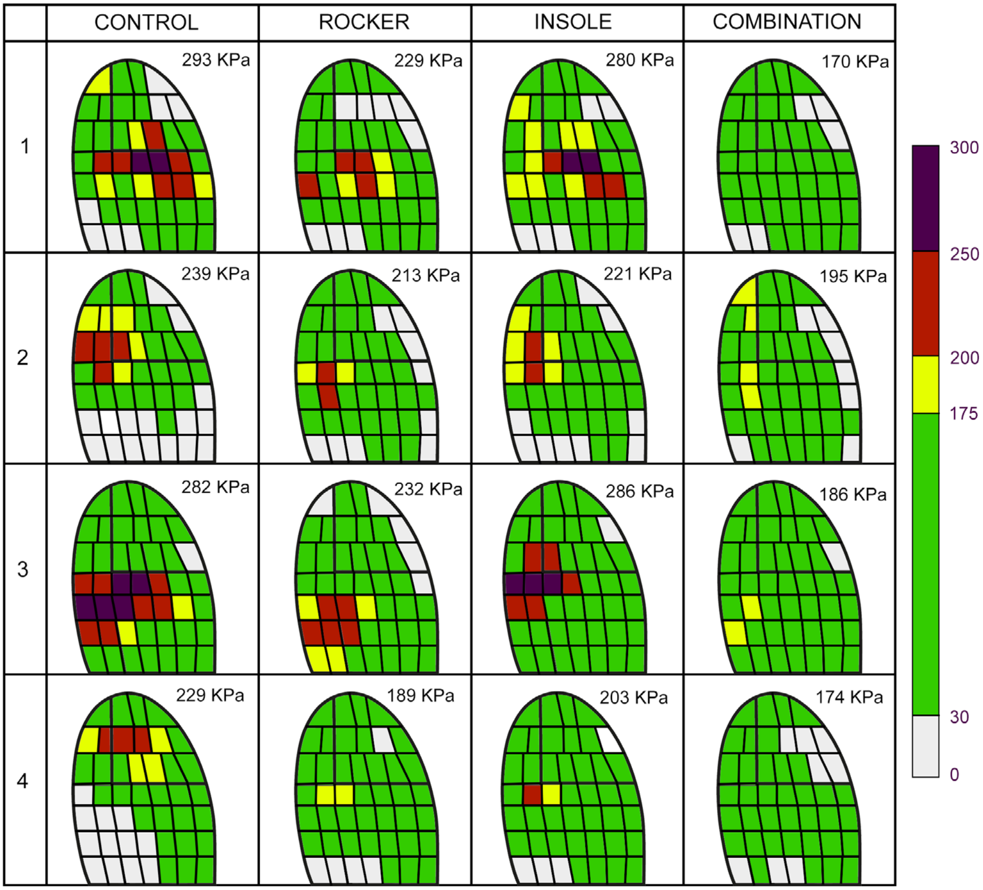

Figure 7.4: *Pressure maps of the forefoot and toes of each participant for all four conditions. Largest peak pressures for the pressure maps are presented in the top right of every cell.*

Spatiotemporal and comfort

The results for the spatiotemporal parameters and comfort are shown in table 7.2. No relevant differences were found between conditions for the stride time, stride length, or stride width in any of the participants.

In participants 1, 2, and 4 the adjustable rocker scored noticeably lower on comfort compared to the control, while in participant 3 comfort was improved. In participants 1 and 2 the self-adjusting insole improved comfort compared to the control. In these two participants comfort for the combination was larger compared to walking with the adjustable rocker profile alone.

Table 7.2: *Spatiotemporal parameters and visual analog scale (VAS) for comfort for each condition in all four participants.*

Participant	Condition	Stride Time (s) Mean ± (SD)	Stride Length (m) Mean ± (SD)	Stride Width (m) Mean ± (SD)	VAS (mm) Max 100
1	Control	1,07 ± (0,03)	1,48 ± (0,05)	0,15 ± (0,02)	59
	Insole	1,08 ± (0,04)	1,49 ± (0,05)	0,09 ± (0,07)	70
	Rocker	1,08 ± (0,02)	1,50 ± (0,05)	0,12 ± (0,03)	7
	Combi	1,06 ± (0,02)	1,50 ± (0,04)	0,07 ± (0,04)	37
2	Control	1,23 ± (0,02)	1,14 ± (0,05)	0,05 ± (0,04)	92
	Insole	1,24 ± (0,02)	1,11 ± (0,03)	0,12 ± (0,03)	90
	Rocker	1,22 ± (0,01)	1,17 ± (0,03)	0,10 ± (0,07)	84
	Combi	1,25 ± (0,03)	1,15 ± (0,05)	0,13 ± (0,02)	91
3	Control	1,20 ± (0,04)	1,22 ± (0,03)	0,09 ± (0,05)	52
	Insole	1,16 ± (0,02)	1,26 ± (0,02)	0,08 ± (0,03)	89
	Rocker	1,18 ± (0,02)	1,26 ± (0,01)	0,09 ± (0,04)	88
	Combi	1,19 ± (0,02)	1,29 ± (0,04)	0,07 ± (0,01)	89
4	Control	1,29 ± (0,02)	1,25 ± (0,02)	0,11 ± (0,06)	72
	Insole	1,31 ± (0,03)	1,28 ± (0,04)	0,11 ± (0,03)	71
	Rocker	1,29 ± (0,03)	1,25 ± (0,03)	0,12 ± (0,04)	54
	Combi	1,32 ± (0,03)	1,25 ± (0,02)	0,10 ± (0,02)	54

Discussion

This case series was the first study in which the newly developed adjustable rocker profile and self-adjusting insole were evaluated when used by patients with diabetes and related neuropathy. When combining the adjustable rocker profile with the self-adjusting insole it was possible to offload PP as high as 293 kPa to below the clinical threshold of 200 kPa. When using both new concepts separately it was not possible to achieve this offloading goal, with exception of the adjustable rocker profile in one participant (participant 4).

The reduction of PP when using only the adjustable rocker profile in patients with diabetes and neuropathy ranged from 26 kPa to 64 kPa. These reductions are lower when compared to the largest reduction (102 kPa) found in Chapter 6, that shows a similar study conducted with healthy participants. A possible explanation could be the fact that in Chapter 6, three rocker settings where measured in each participant and the setting that resulted in the best offloading at a targeted region of interest was chosen for further examination, whereas in the current study only one rocker setting was tested (based on the results of Chapters 4 and 6). The possible settings were based on the settings that resulted in the largest offloading of targeted regions of interest in previous studies (Chapter 4 and 6). However, due to the between subject variability in those studies, other rocker settings could have resulted in larger offloading in the current study population. Also, due to differences in gait between healthy young adults and older adults with diabetes that have neuropathy, the efects of the rocker settings could be different. Further evaluation of different rocker settings is therefore needed in patients with diabetes and neuropathy to investigate the ulcer prevention potential of the adjustable rocker.

It is important to note that while the focus in this study was at the forefoot and toes increases in PP between 41 kPa and 91 kPa were found at the heel in every participant when using the adjustable rocker profile separately or combined with the self-adjusting insole. This increase can be explained by the lack of shock absorption as a result of the three layers of carbon and hard EVA (70 durometers, shore A) that are used in the adjustable rocker prototype directly underneath the heel.

In the current study the pressure threshold of the self-adjusting insole (also referred to as $Threshold_{in}$) was changed to 190 kPa, as recommended in the previous studies with healthy participants. The use of the self-adjustable insole alone resulted in reductions up to 26 kPa, which is similar to the reductions found in previous studies with healthy participants (Chapter 5 and 6). While the change in threshold did not result in the expected larger PP reductions when the self-adjusting insole was used alone, it did result in the ability to offload large PP when combined with the self-adjusting rocker profile. The difference between PP in the combination and the adjustable rocker profile indicates that the rigid outsole is beneficial for the offloading capabilities of the self-adjusting insole as PP reductions are larger compared to using the self-adjusting insole alone, with reductions up to 59 kPa. More important, in the cases where PP were above 200 kPa when only using the adjustable rocker, the combination with the self-adjusting insole ensured offloading to below this clinical pressure threshold.

None of the experimental conditions seem to affect any of the spatiotemporal parameters, as the mean stride time, stride length, and stride width showed no substantial differences between conditions. However, in two cases (participant 1 using the self-adjusting insole and participant 2 using the adjustable rocker profile) the standard deviation for stride width was slightly increased compared to the control condition, indicating more variation between steps. An increase in stride width variation can indicate a decrease in stability[22,23]. While the increase in variation was small, further evaluation of stability while using both the adjustable rocker profile and self-adjusting insole is needed.

The self-adjusting insole was perceived as comfortable as the control condition, and by two participants as more comfortable. The adjustable rocker profile seemed to be the least comfortable. In one participant the VAS-score was 7/100, which indicates that it was very uncomfortable. Comfort was increased when the self-adjusting insole was added to the adjustable rocker profile in two participants. In two other participants the combination was as comfortable as the adjustable rocker profile. As mentioned before, the adjustable rocker profile allows poor shock absorption at the heel because of the rigid materials in the prototypes at this area. This is likely the main contributor to the low comfort scores of the adjustable rocker profile. Another contributor could be the increased weight of the adjustable rocker profile, which is over two times the weight of the unmodified shoe (increase between 244 and 307 grams per shoe). Both should be addressed in a redesign of the current prototypes. It is important to note that the VAS scores only provide a limited indication of the perceived comfort as participants only used the conditions for a few minutes.

The most important limitation in this study is the number of included participants, as it is too low for any form of generalization of the results in this study. This was, however, the first time both the adjustable rocker profile and the self-adjusting insole were tested in patients that are considered to be at risk of developing DFU, and the results provided a first impression in the functionality of both concepts, especially because of the similar trends in offloading between conditions in all four participants. Another limitation is the fact that only one rocker setting (out of three rocker settings) was used in each participant based on the location of the largest PP. The used rocker setting may therefore not have been the rocker setting that results in the largest offloading of PP. However, it was chosen to have only one rocker setting to keep the duration of each experiment to approximately one hour, as we believed that longer durations would result in too much burden for the participants.

Conclusion

This was the first study in which the newly developed adjustable rocker profile and the self-adjusting insole were tested in patients with diabetes and neuropathy. When combining both concepts it was possible to offload all dangerous PP (up to 293 kPa) in all four participants to below 200 kPa, which is considered to be a safe pressure threshold and is believed to help prevent diabetic foot ulcer development. While these results are promising, a larger clinical trial with more participants is needed to validate the current results.

Acknowledgements

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GENERAL DISCUSSION

Design

The aim of this thesis was to design and evaluate two new pressure reducing footwear concepts for the prevention of diabetic foot ulcers (DFU). These concepts needed to be adjustable to allow for easy individualization and to accommodate for changes in the location of high peak pressures (PP) over time.

Adjustable rocker profile

The first design that is introduced in this thesis is the adjustable rocker profile that allows for quick changes of the apex position and the apex angle without the need of an orthopaedic workshop. The use of a rail and slider mechanism allows for continuous adjustments of the apex position anywhere between 50% and 70% of the total shoe length. The apex angle can range anywhere between 40˚ and 140˚. While Chapter 3 described lower increase in PP at the Hallux when dorsiflexion at the metatarsal phalangeal joints is allowed, it was decided that the implementation of flexibility that allows this motion into the rail mechanism would be too complicated for manufacturing and might result in early break down of the shoe, and was therefore not incorporated in the design.

Self-adjusting insole

The second concept that was introduced in this thesis was the self-adjusting insole. This innovative insole design consists entirely of hexagonal shaped elements, each having a supporting surface of 1.46 cm^2. The elements collapse when pressures exceed a set threshold (referred to as $Threshold_{in}$) causing the supporting surface to drop down. This results in immediate offloading at the location of the collapsed element as pressures are redistributed across neighbouring elements of which the supporting surface did not drop down. The collapsed elements return to their original shape when pressures are considerably lowered, which will occur during the swing phase of gait. The self-adjusting insole is flat, and as it remains rigid until the pressure threshold is exceeded it may increase tactile feedback. This is expected to be beneficial for postural balance and stability.

Combination

A study by Postema et al (1998) showed that the pressure reducing effects of rockers and custom insoles can be added, indicating that larger pressure reductions can be achieved when a combination of both a rocker profile and a custom insole is used compared to using either separately[1]. To increase the offloading effects the adjustable rocker profile should therefore be used together with the self-adjusting insole or any other pressure reducing insole, while the self-adjusting insole should be combined with the adjustable rocker or any other pressure reducing rocker profile.

Evaluation

Functions

Adjustable rocker profile

Figure 8.1 shows the function analysis that describes the internal functions that the adjustable rocker profile needs to have as presented in Chapter 2. The adjustable rocker profile needs to allow for manual adjustments to the apex, based on pressure measurements from an external system. This is achieved by sliding two knobs, that together function as the apex, across two rails. To loosen and fixate the knobs, and with that the apex, a bolt in the centre of both knobs is used.

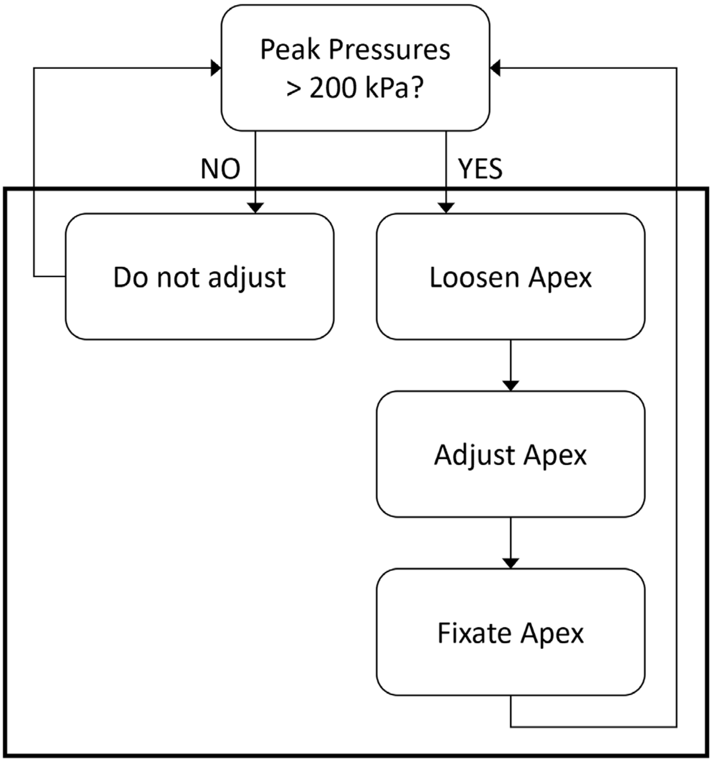

Figure 8.1: *Function analysis for the adjustable rocker profile as presented in Chapter 2.*

Self-adjusting insole

The function analysis that describes the internal functions that the self-adjusting insole needs to have is shown in Figure 8.2. The self-adjusting insole needs to function in such a way that when PP exceed 200 kPa the insole surface should automatically lower at the location of these dangerous pressures. For PP below 200 kPa the insole surface should not adjust. This functionality is achieved by the use of the designed elements of which the entire self-adjusting insole is made. The buckling behaviour of the elements results in the elements dropping down when pressures exceed the buckling threshold (which is referred to as $Threshold_{in}$). This threshold can be adjusted by changing the wall thickness and/or the angle of the walls in the lower part of the elements. Finally, the insole surface should restore during the swing phase of gait, when pressure is removed. This was achieved by the elasticity of the material, which causes the element to return to its original shape once no pressure is applied.

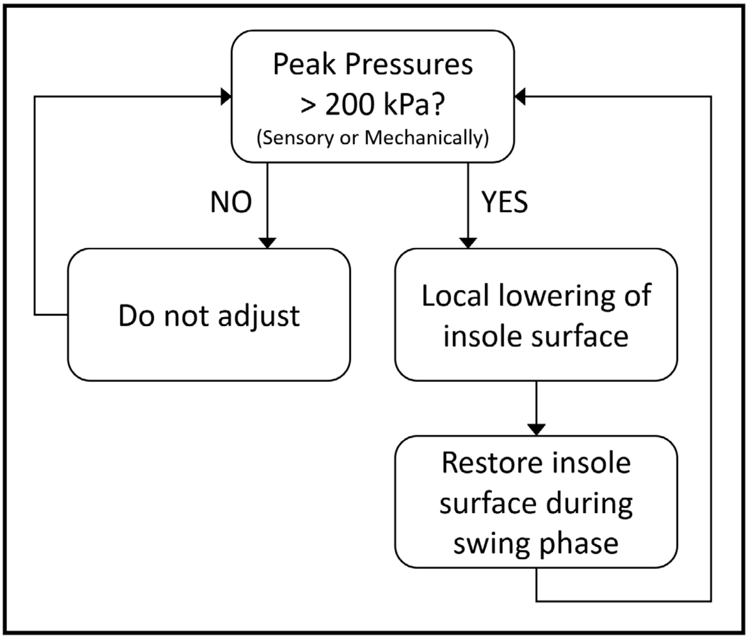

Figure 8.2: *Function analysis for the self-adjusting insole as presented in Chapter 2.*

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Requirements

Table 8.1 shows the current status of the adjustable rocker profile for all requirements and what future actions are needed to fulfil a requirement.

PP reduction with the adjustable rocker profile

On a group level it was possible to reduce PP from between 221 kPa (n=12, Chapter 6) and 230 kPa (n=13, Chapter 4) to below 200 kPa with the adjustable rocker profile in healthy participants, while on an individual level PP as high as 260 kPa could be successfully reduced. However, when tested in people with diabetes and neuropathy, it was only possible to reduce PP to below 200 kPa in one out of four participants using only the adjustable rocker profile. In this particular case the PP was relatively low (229 kPa) in the control condition. There are a couple of factors that might have resulted in this difference in PP reduction on an individual level. Firstly, there was a difference in how the used rocker setting was determined. In Chapter 6 the three apex settings that seemed most effective (based on the results in Chapter 4) were all measured and the setting that resulted in the most PP reduction at a determined region of interest (ROI) was used for the combination condition and for further data analysis. For the patient case series the ROI was determined, and the setting that resulted in the largest reduction was based on the findings in our previous studies with healthy participants. One of the other possible apex settings might have resulted in better offloading especially considering the between subject variability in Chapters 4 and 6. The second factor is the differences in gait between healthy young adults and older adults with diabetes that have neuropathy, which might affect the offloading effects of the rocker settings. Also, PP are already elevated in diabetics with neuropathy compared to healthy adults. Therefore, initial PP might have been too high to offload with a rocker profile alone the individual cases were PP was over 260 kPa in the control condition. Finally, the rocker settings were based on the location of the Metatarsophalangeal heads (MTHs) for a more personalized approach compared to basing apex positions and angles on properties of the shoe. We expected to find more similarities in the effects on in-shoe PP for different rocker settings between participants. However, there was still a large variability between participants for most settings. This indicates that there are other variables that influence the offloading effects of a rocker setting. One interesting variable might be the foot progression angle, which is the angle formed between the longitudinal axis of the foot and the forward line of progression during walking[2]. Different foot progression angles may lead to different orientations of the MTHs, and with that of the apex, to the forward line of progression. This could result in different effects of different rocker settings between individuals with different foot progression angles. From the above we can conclude that the first functional requirement, which states that the adjustable rocker profile must reduce PP to below 200 kPa or by 30%, was partly achieved and further evaluation is needed. Most of the unknowns described above could be evaluated in a future patient study in which the effects of the three rocker settings from Chapter 6 and 7 on in-shoe PP are evaluated. During the in-shoe pressure measurements one should simultaneously measure the foot progression angles. Using statistical methods like multilevel analysis it would be possible to determine if the foot progression angle affects the offloading effects of different rocker settings.

Table 8.1: *the current status of the adjustable rocker profile for all requirements and future actions that are needed to fulfil a requirement.*

ID	Requirement	Status	Action
R-1. Functional	*The adjustable rocker profile must;*		
R-1.1	Reduce PP to below 200 kPa or by 30%	Partly achieved	Further evaluation
R-1.2	Allow for rocker axis adjustability	Achieved	None
R-1.2.1	Apex position: 50% - 65% of the total shoe length	Achieved	None
R-1.2.2	Apex angle: 70˚ – 100˚	Achieved	None
R-1.2.3	Without the need of an orthopaedic workshop	Achieved	None
R-1.2.4	Within 5 minutes	Achieved	None
R-1.3	Be suitable for users that weigh less than 135 kg	Not tested	Further evaluation
R-1.4	Be suitable for users with shoesizes 36-46EU	Achieved	None
R-1.5	Be suitable for users that fit in conventional shoes	Achieved	None
R-1.6	Be able to be used 7 days a week	Not tested	Further evaluation
R-1.7	Have a lifespan of more than 1 year	Not tested	Further evaluation
R-1.7.1	Repeatability > 3000000 steps	Not tested	Further evaluation
R-2. Size	*The adjustable rocker profile must;*		
R-2.1	Fit the outline of the used shoe	Achieved	None
R-2.2	Not increase the shoe height by more than 25 mm	Achieved	None
R-2.3	Weigh less than 1000 grams per pair	Partly Achieved	Redesign
R-3. Safety	*The adjustable rocker profile must;*		
R-3.1	Not decrease the stability during gait compared to non-adjustable rocker profiles	Not tested	Further evaluation
R-3.2	Not adjust during walking	Partly Achieved	Further evaluation
R-4. Ergonomical	*The adjustable rocker profile must;*		
R-4.1	Be perceived as comfortable	Partly achieved	Redesign
R-5. Aesthetical	*The adjustable rocker profile must;*		
R-5.1	Not be less attractive to wear compared to current ulcer preventive footwear	Not tested	Further evaluation
R-6. Cost	*The adjustable rocker profile must;*		
R-6.1	Cost less than 100 euro for manufacturing per pair (excluding shoes)	Not achieved	Redesign

Other requirements for the Adjustable Rocker Profile

Table 8.1 shows that several requirements are achieved with the current prototype of the adjustable rocker profile. All requirements describing the rocker axis adjustability (R-1.2.1 till R-1.2.4) are achieved as the apex position can be adjusted between 50% and 70% of the total shoe length, a minimum apex angle of 40° and a maximum apex angle of 140° can be achieved (when the apex is positioned at around 60%), only a screwdriver was needed for the adjustments, and the adjustments took roughly one minute per shoe during the experiments. Although only sizes 36-45 EU prototypes were made it would have been possible to make a size 46 EU, fulfilling requirement R-1.4. As the adjustable rocker profile mechanism is placed between the outsole and the upperpart of conventional shoes (Chris/Meghan, Dr Comfort, Mequon, WI, USA), it is possible for people that fit in conventional shoes to use the adjustable rocker profile prototype (R-1.5). The adjustable rocker profile mechanism follows the outlines of the used shoes, and resulted in an increase in height of 23 mm compared to the original shoe, fulfilling two out of the three size requirements (R-2.1 and R-2.2).

The weight requirement (R-2.3) is partly achieved and the cost requirement (R-6.1) was not achieved, which is mainly the result of the fact that the prototype was created to provide proof of the adjustable rocker profile concept using materials that were on hand at Dr Comfort or easy to purchase from local hardware stores. The weight requirement of 1000 grams per pair is achieved for the sizes 36 EU to 40 EU. For the other sizes the weight is up to 1136 grams per pair (size 45 EU). Most of the weight increase is caused by the rail (approximately 200 grams) which is constructed out of three 2 mm thick carbon layers. The current prototype could already weigh less by replacing the 2 mm carbon layers by 1 mm layers. Also, more material could be removed to make the rail lighter for instance at the heel, which is now solid, and from the middle carbon layer. Finally, the 3 mm Polyethylene layer that keeps the knobs from digging into the original outsole, which accounts for an increase of approximately 80 grams, could also be thinner or be made out of lighter materials. While these options would reduce the weight significantly it would make the manufacturing of the rail more complex and thus more expensive. This would not be favourable for the cost requirements of 100 euro for manufacturing per pair (R-6), which is already not met with the current prototype because of the complex and time consuming manufacturing method. Therefore, a redesign based on manufacturing methods that allow for mass production of the rail is recommended.

With methods like injection molding a two part construction of the rail is possible. The rail could be partly hollow and reinforced with ribs parallel to the longitudinal axis of the shoe to provide enough stiffness while still being lightweight. Also, additive manufacturing could allow for more complex weight reducing and stiff designs that can be made in one piece.

None of the knobs got loose, which would have resulted in adjustments of the rocker axis during walking, during the experiments. While this only shows that requirement 3.2 is met during short time use, it seems promising for long time use. Therefore, this requirement is considered partly achieved. The effects of long term use should be further evaluated. The adjustable rocker profile was considered comfortable by two patients in Chapter 7, it was also perceived as very uncomfortable by one of the included patients. As mentioned before, the weight of the current prototype is too high, which may have contributed in the poor comfort score. Furthermore, a lack of shock absorption, caused by the hard materials used at the heel, is likely to have a negative effect on comfort. While, some of the participants considered the adjustable rocker profile to be comfortable the results only provide information on short time use. Therefore, the ergonomical requirement that describes that the adjustable rocker profile should be perceived as comfortable (R-4.1) is considered partly achieved. A redesign is recommended to improve comfort. The beforementioned weight reductions are expected to have a positive effect on perceived comfort. Also, more shock absorption at the heel is recommended, which on the short term can be achieved in the current design by removing some of the carbon at the heel and filling it with softer materials like EVA. However, when already considering additive manufacturing methods like 3D-printing for weight reductions one could incorporate shock absorbing structures at the heel.

Several requirements were not tested, as the main focus of this thesis was to evaluate the effects of the new adjustable concepts on in-shoe PP. The effect of different rocker settings on stability could already be tested with the current prototype and could provide useful information for the redesign. For all functional requirements that were not tested (R-1.3, R-1.6, and R-1.7) a stress and durability test needs to be performed, which is recommended after the redesigns mentioned before as different materials and manufacturing methods are likely to be used. Finally, As the adjustable rocker profile prototype was built to be effective and not aesthetically appealing it made no sense to ask patients what they thought about the looks of the adjustable rocker profile. However, aesthetics play an important role in adherence and should therefore be improved. A possible aesthetical improvement could be achieved when the rocker settings can be adjusted from the inside of the shoe. This would make it possible to hide the rail mechanism from the outside of the shoe with an elastic outsole, which would eliminate the open space in the sole and the use of the Velcro strap at the toes.

Reduction of PP by the self-adjusting insole

Table 8.2 shows the current status of the self-adjusting insole for all requirements and what future actions are needed to fulfil a requirement. In healthy participants it was only possible to effectively reduce PP to below 200 kPa when initial PP was up to 210 kPa. These poor offloading capabilities were likely caused by the used $Threshold_{in}$ of approximately 144 kPa, which probably resulted in too many supporting surfaces of the elements to drop down, as PP at many locations was over this threshold in the control condition. When a large area drops down, there are not enough possibilities for redistribution across neighbouring elements. As the aim was to offload PP of 200 kPa or larger, $Threshold_{in}$ should be just below 200 kPa. Therefore, $Threshold_{in}$ was increased to approximately 190 kPa in the patient study in Chapter 7. While PP reductions still were not as large as expected when using the self-adjusting insole in a conventional shoe with a flexible outsole it was possible to reduce PP from as high as 239 kPa to below 200 kPa when combined with the adjustable rocker profile which has a rigid outsole. Because of the results discussed above the first functional requirement, which describes reduction of PP to below 200 kPa [3] or (when this is not possible) by 30%[4], as recommended by guidelines for the prevention of DFU is considered to be partly achieved. For more effective offloading of the self-adjusting insole a redesign is needed. Small changes in the current design might already result in more effective offloading. One change could entail smaller elements which results in more elements in each insole. This could result in more precise offloading, meaning that a smaller area of the insole surface drops down. Also, smaller elements might be beneficial at the outer edges of the self-adjusting insole, as in the current design there are many partial elements at these locations that do not function as complete elements, meaning they simply compress or fold away instead of dropping down when pressures exceed $Threshold_{in}$. Another change to the current design could be to increase the possible vertical displacement of each element. Especially in the patient study we found large areas with pressures over 200 kPa, which results in a large area of the self-adjusting insole surface to drop down. While it was possible to reduce the area with PP over 200 kPa when walking with the self-adjusting insole, the remaining dangerous PP were found very locally. This might indicate that the current vertical displacement (approximately 3 mm) does not create enough depth for perturbances at the plantar surface of the diabetic foot, resulting in loading of the element after maximal displacement. Although increasing the maximal vertical displacement of the elements might result in better offloading capabilities, it should be noted that too much vertical displacement might cause problems with stability. Therefore, the trade-off between offloading and stability should be further investigated.

The buckling mechanism in the elements of the self-adjusting insole results in automatic adjustment of the supporting surface to pressures over $Threshold_{in}$. With a $Threshold_{in}$ just below 200 kPa the insole automatically adjusts to pressures of 200 kPa or larger. The elements have a surface of 1.46 cm^2 that drop down approximately 3mm, and make up the entire insole surface. Therefore, it can be concluded that the second functional requirement (I-1.2) was achieved, fulfilling all its sub-requirements (I-1.2.1 till I-1.2.3).

Table 8.2: *the current status of the self-adjusting insole for all requirements and future actions that are needed to fulfil a requirement.*

ID	Requirement	Status	Action
I-1. Functional	*The self-adjusting insole profile must;*		
I-1.1	Reduce PP to below 200 kPa or by 30%	Partly achieved	Redesign
I-1.2	Adjust automatically to pressures of 200 kPa or larger	Achieved	None
I-1.2.1	At the areas at risk (MTH1-5 and first toe)	Achieved	None
I-1.2.2	Lowering insole surface only locally (area below 1.50 cm^2)	Achieved	None
I-1.2.3	Have a maximum vertical displacement of 5 mm when adjusting to pressures	Achieved	None
I-1.3	Be suitable for users that weigh less than 135 kg	Not tested	Further evaluation
I-1.4	Be suitable for users with shoesizes 36-46EU	Achieved	None
I-1.5	Be suitable for users that fit in conventional shoes	Achieved	None
I-1.6	Be able to be used 7 days a week	Not tested	Further evaluation
I-1.7	Have a lifespan of more than 1 year	Not tested	Further evaluation
I-1.7.1	Repeatability > 3000000 steps	Not tested	Further evaluation
I-2. Size	*The self-adjusting insole profile must;*		
I-2.1	Have a maximal thickness of 9 mm	Achieved	None
I-2.2	Fit inside the used Dr Comfort shoe	Achieved	None
I-2.3	Weigh less than 200 grams per pair	Achieved	None
I-3. Safety	*The self-adjusting insole profile must;*		
I-3.1	Not decrease the stability during gait compared to walking without an insole	Not tested	Further evaluation
I-3.2	In case of electronics have;	N/A	None
I-3.2.1	Enclosure leakage current of less than 300 µA	N/A	None
I-3.2.2	Patient leakage current of less than 10 µA	N/A	None
I-4. Ergonomical	*The self-adjusting insole profile must;*		
I-4.1	Be perceived as comfortable	Partly achieved	Further evaluation
I-5. Cost	*The self-adjusting insole profile must;*		
I-5.1	Cost less than 70 euro for manufacturing per pair	Partly achieved	Further evaluation

Other requirements for the self-adjusting insole

All size requirements were achieved as the insole was 9 mm thick (I-2.1), the outlines of the self-adjusting insole were designed to fit the used Dr Comfort shoes (I-2.2), and weigh less than 200 grams for at least all sizes up to 46EU (I-2.3) as a pair of size 37 EU weighed 104 grams and a pair of size 45 EU 152 grams.

Similar to the adjustable rocker, perceived comfort was measured in four participants. While the self-adjusting insole was considered comfortable in all participants, it only provides information on short term use in a very small sample size. Therefore, the ergonomical requirement, describing that the self-adjusting insole should be perceived as comfortable, was partly achieved. Further evaluation of the perceived comfort should be evaluated during longer use in a larger group of patients. While material costs for the prototypes were far below 70 euros for each pair of self-adjusting insoles (approximately 10 euros) the current 3D-printing process takes too much time for mass production, with printing times up to 17 hours per pair. The long printing time was mainly due to the 3D-printing method that was used. The self-adjusting insoles were printed with Fused Deposition Modelling (FDM) printers using flexible filament. Other 3D-printing techniques like Continuous Liquid Interface Production can be over ten times faster[5,6] and have already been used by ADIDAS for the production of midsoles. Other options that are currently used in mass-production can also be explored to make the self-adjustable insoles profitable. For instance, the solid top part of the element and the hollow bottom part could be manufactured separately with techniques like injection moulding, after which they could be glued or welded together. This way sheets filled with these elements could be made, which can be cut to the shape of any shoe.

As the self-adjusting insole is still a prototype for proof of concept, it made no sense to already test durability and maximal loading. While it is expected that the used thermoplastic Polyurethane (Ninjaflex) is expected to withstand repeated stresses, the manufacturing method (FDM) is likely to result in failure when used fulltime because of layer separation. The effect of the self-adjusting insole on stability could already be investigated with the current prototypes. This could be incorporated in the beforementioned redesign process, by for instance measuring margins of stability[7] while walking with the current prototypes and new prototypes that allow for more vertical displacement.

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Reduction of PP for the combination of concepts

To prove the functionality of both concepts experiments in the current thesis were mainly focused on the first functional requirement, which describes reduction of PP to below 200 kPa [3] or (when this is not possible) by 30%, as recommended by guidelines for the prevention of DFU[4]. As discussed above, this was only partly achieved when using the adjustable rocker profile and the self-adjusting insole separately. However, combining the adjustable rocker profile and the self-adjusting insole resulted in large PP reductions both in healthy participants and patients with diabetes and related neuropathy. Moreover, dangerous PP could successfully be reduced to below 200 kPa in the patient case series described in Chapter 7. Thus when combining both concepts the first functional requirement is considered to be achieved.

Goals

Now that the functions and requirements have been discussed the main question that remains is; *Do the new concepts solve the problems for what they were designed?* In other words, did the adjustable rocker profile and the self-adjusting insole meet their intended goals. In Chapter 2 the problems and the goals of the concepts were defined with the following cause and effect diagrams (Figure 8.3).

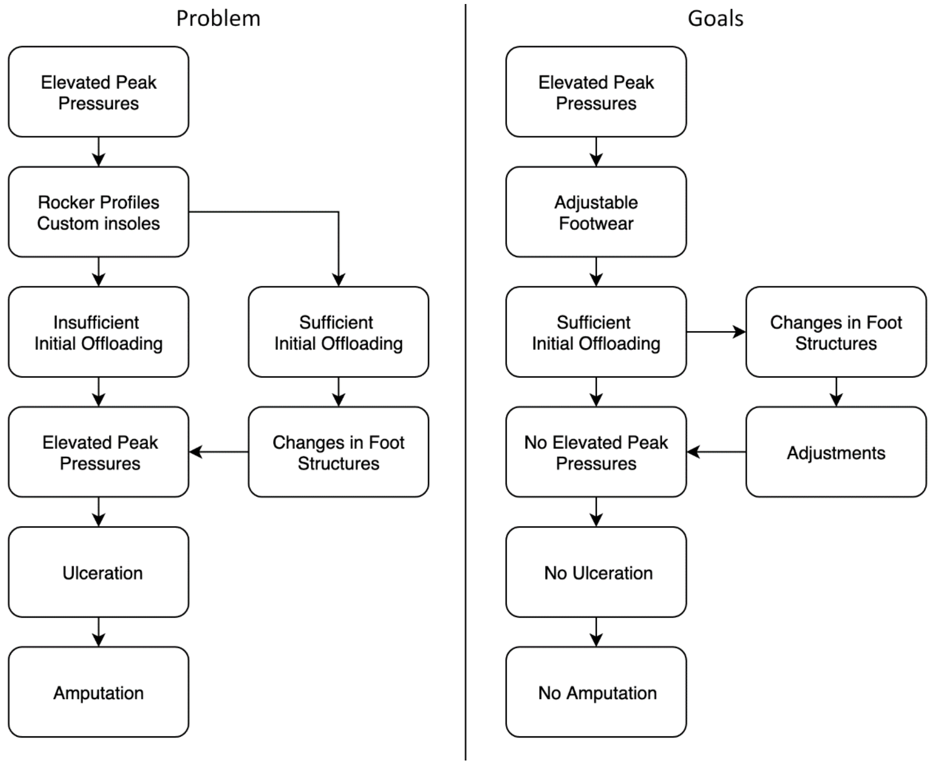

Figure 8.3: *Cause and effect diagrams for the often occurring problems with commonly prescribed pressure reducing devices (left) and the goals of the concepts developed in this thesis (right).*

The goals were achieved when combining both the adjustable rocker profile and self-adjusting insole. The combination of both resulted in sufficient offloading (PP < 200 kPa) in participants with diabetes and neuropathy (Chapter 7). As the insole is not shaped to the foot, but automatically adjusts to dangerous PP at any location it will account for changes in foot structures that lead to a shift in the location of pressure spots. In case of large changes in the location of pressure spots adjustments to the apex might be needed, which can easily be achieved using the adjustable rocker profile.

Comparison to other solutions

Pressure reducing solutions

There have been multiple studies that evaluated the effects of insoles and rocker profiles on in-shoe pressures. Two studies that evaluated the effects of different rocker settings on in-shoe pressures using the Pedar-X system, which allows for a good comparison to the adjustable rocker profile. The study by Chapman et al. (2013) [8] reported reductions of PP up to 39% (initial PP approximately 220 kPa), while reductions as high as 55% (initial PP not reported) were reported in the study by Van Schie et al. (2000) [9]. With the adjustable rocker profile the largest reductions on group level were 27% (initial PP 230 kPa), while on an individual level reductions as high as 40% in healthy participants were reported in this thesis. It should be noted that in the previous studies the walking speed was fixed at 1 m/s (± 10%), while in the current thesis participants could walk at their preferred walking speed which resulted in higher walking speeds (Chapter 4: 1.54 (±0.19) m/s, Chapter 6: 1.40 (±0.10) m/s). Also, the mean bodyweight was lower in the Van Schie study (71.5 (±7.1) kg) compared to the studies in this thesis (Chapter 4: 76 (±8.2) kg, Chapter 6: 78 (±9.0) kg), while bodyweight was higher in the study by Chapman (86 (±12.4) kg). As increased walking speed and/or bodyweight results in larger PP [10] these differences likely explain why the reductions with the adjustable rocker profile are more comparable to the study by Chapman et al. than to the study by Van Schie et al. A study by Guldemond et al. (2007) [11] showed great PP reductions in diabetic patients with neuropathy when using different insole shapes. Adding arch support with extra height and a metatarsal dome reduced PP from 231 kPa to 150 kPa at the medial forefoot, and PP from 210 kPa to 128 kPa at the central forefoot. With the current design of the self-adjusting insole PP it was possible to effectively reduce similar initial PP to below 200 kPa, especially when a rigid outsole was used. Moreover, the addition of a medial arch can result in decreased stability compared to flat insoles[12], which is unwanted especially in diabetics with neuropathy as their stability has already been compromised. Also, when it comes to stability the self-adjusting insole is likely more favourable compared to the insole shapes used in the study by Guldemond et al. (2007), as a flat rigid surface enhances stability compared to insoles that are shaped to the foot[12]. In a study by Bus et al. (2011) footwear of diabetics with neuropathy was optimized based on pressure at a specific ROI. Both insole modifications and small rocker profile alterations were performed in the optimization process. The relative reductions found at the ROIs in this study (group level: 30.2%, individual level: 50.0%) were comparable to those found in Chapter 6, where the combination of the adjustable rocker profile and the self-adjusting insole were evaluated in healthy participants (group level: 25.3%, individual level: 54.3%). The combination of the adjustable rocker profile and the self-adjusting insole resulted in reductions between 18.4% and 42% in diabetic patients with neuropathy at the entire forefoot and toes area instead of a specific ROI, but more importantly PP as high as 293 kPa were reduced to below 200 kPa. Bus et al. was explained that larger rocker profile modifications that needed addition of midsole materials or completely new rocker profiles were not possible in their study as it would have required special machinery and cost too much time. This is where the advantages of the adjustable rocker profile are shown, as completely new rocker settings can be achieved within seconds, using only a screwdriver. Finally, compared to other insoles the self-adjusting insole has the advantage that it needs no customization, and will adjust automatically to dangerous PP without any manual modifications.

There has been a development in Geneva with a similar aim as that of the self-adjusting insole. A paper (and patent) by Grivon et al (2015) describes a soft magneto-rheological shock absorber with a pressure sensor on top that could be used in a smart shoe for patients with diabetes to prevent DFU[13,14]. The design allows for controllable variable stiffness of the shock absorber based on the pressure that is applied to it. In other words, one could program a pressure threshold, if the pressure at the location of the shock absorber exceeds this threshold, the shock absorber becomes less stiff allowing for cushioning. The diameter of each shock absorber is 15mm, which is comparable to the self-adjusting insole elements. The height of each shock absorber is 28 mm. They proposed to place multiple shock absorbers at the forefoot and heel area in the midsole of a shoe, and a microcontroller and battery at the midfoot. Compared to the self-adjusting

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insole the proposed smart shoe design does allow for a controllable threshold and stiffness of each shock absorber, where the self-adjusting insole only allows for a set threshold which might be favourable. However, the system is far more complex than the self-adjusting insole which causes the system likely to be far more expensive. Also, the use of fluids and batteries will definitely result in the smart shoe to be heavier than a shoe combined with a self-adjusting insole. Finally, there are far more components that can break down resulting in malfunctioning of the device.

Solutions for fundamental problems

In Chapter 1 the pathways to DFU were described using a cause and effect diagram (Figure 8.4) that showed that there are more fundamental problems involved in DFU development then elevated PP alone. After diabetes, neuropathy is considered to be the most important fundamental problem in DFU development as it contributes to 90% of all DFU[4,15-17]. There is a major development in research surrounding diabetic neuropathy. A study by Najafi et al (2017) showed that it was possible to decrease insensitivity at the plantar surface of the foot by applying 60 minutes of electoral stimulation on a daily basis[18]. If sensation could be restored in neuropathic feet it would solve one of the fundamental problems that causes DFU, and would therefore be more effective than any pressure reducing shoe or insole when it comes to preventing DFU. While the results are very promising, further research is needed to see how these results hold over a longer period of time as the effect was measured in a six week timeframe.

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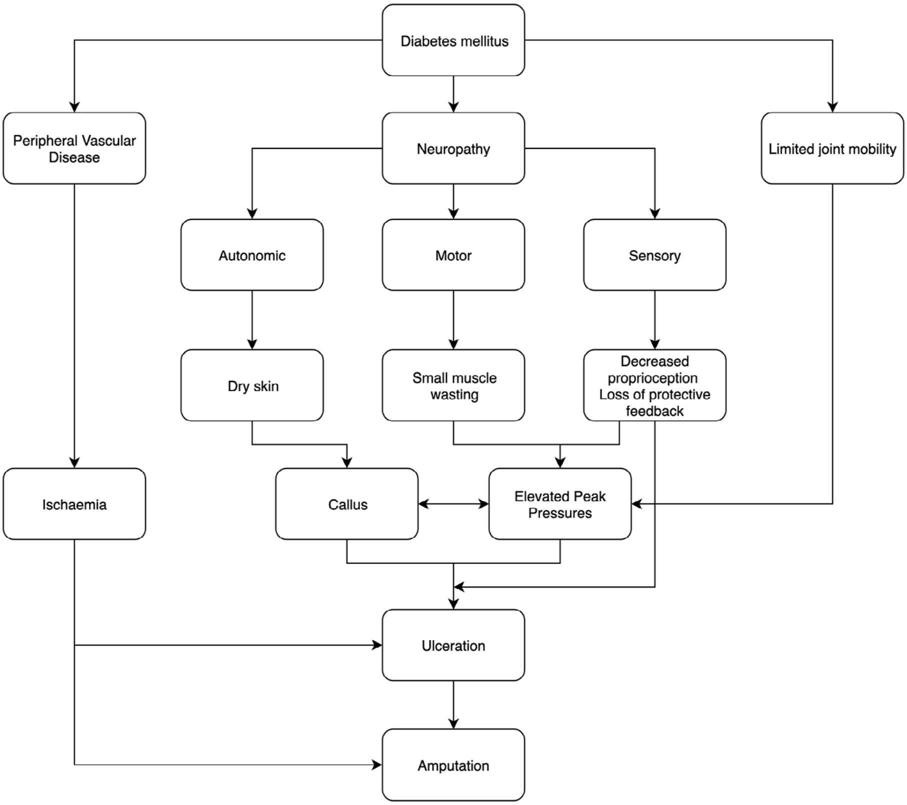

Figure 8.4: *Pathways to diabetic foot ulcers*[15]

Thesis limitations

The main limitation of this thesis is the number of Diabetic patients that have been included. As only four patients were included it is still not possible to generalize the results found in this thesis. The case study does however show the pressure reducing potential of both the adjustable rocker profile and the self-adjusting insole, especially when combined.

Another limitation is the fact that the main focus of this thesis was on reducing PP to below 200 kPa or when this is not possible by at least 30%, as recommended for the prevention of diabetic foot ulcers[3,4]. Especially the self-adjusting insole was designed with the idea of not only reducing PP that are considered too high, but also not reducing postural stability. However, we did not perform any experiments to evaluate the effects of the self-adjusting insole on postural stability.

Finally, the results in Chapter 5 and 6 showed that the $Threshold_{in}$ of the self-adjusting insole configurations were far from optimal. While the working mechanism of the self-adjusting insole was proven in these chapters, it was not possible to offload large PP and increases was sometimes increased as a result of the chosen $Threshold_{in}$. Changing the $Threshold_{in}$ to 190 kPa in Chapter 7 resulted in better offloading capabilities, especially when combined with the adjustable rocker profile.

Further development/Valorisation

Adjustable rocker profile

In the (near) future the adjustable rocker profile concept could be used in two different ways to aid in the prevention of DFU. The first way would be to use the current adjustable rocker profile combined with a pressure measuring system like Pedar-X as an instrument to determine the apex position and angle that results in optimal PP reduction for each individual. Currently these parameters are based on empirical knowledge. Using the adjustable rocker profile as an instrument would therefore allow for a more standardized approach of the rocker profile design which is based on pressure measurements. The second way to prevent DFU with the adjustable rocker profile is to further develop the shoe for retail, as intended, allowing for easy rocker adjustments whenever the location of the PP shift. Currently, we are talking to companies about the possibilities for further development of the adjustable rocker profile into a version suitable for series production.

Self-adjusting insole

The self-adjusting insole design was already considered very promising and innovative which resulted in the University of Groningen to apply for patency (patent application can be found in appendix: Patent self-adjusting insole). After the small redesigns and further evaluation mentioned before there are multiple possibilities to market the self-adjusting insole. One would be to produce entire sheets filled with the elements. Different sheets can have different thresholds. These sheets can be sold to orthopaedic shoe technicians or pedorthists who can cut the sheets to fit any shoe. Another, maybe more profitable way, might be to sell the self-adjusting insoles directly to customers. Finally, the elements of the self-adjusting insole could also be used in completely different products that encounter problems with peak pressures. There have been suggestions from different parties on using them in for instance prosthetic sockets, exoskeletons, and chairs.

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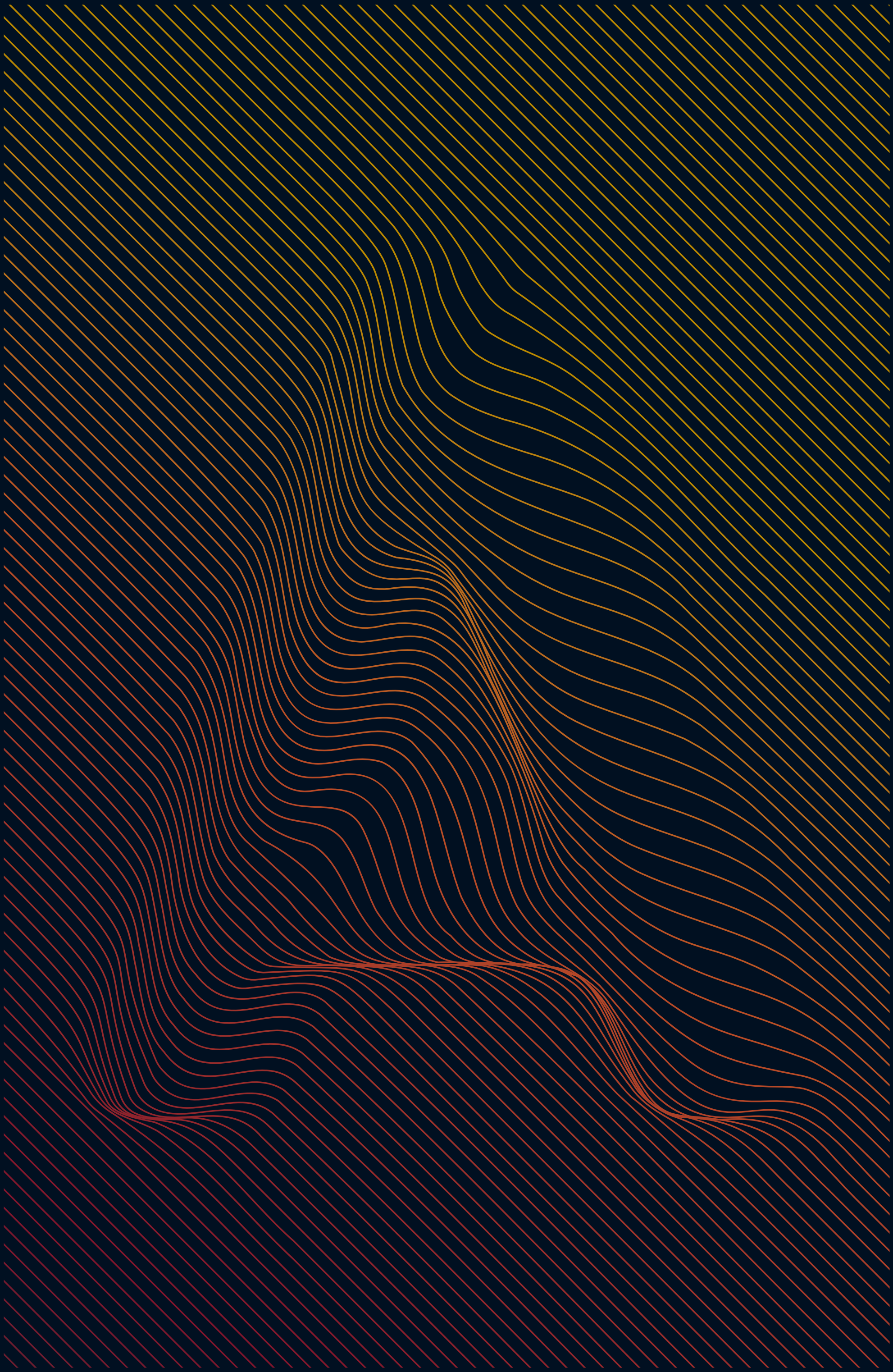

APPENDICES

SUMMARY

Worldwide there are over 422 million people with diabetes. Up to 34% of them will develop at least one diabetic foot ulcer. These ulcers are extremely dangerous and can eventually result in complete amputation of the affected leg. Elevated pressures at the plantar surface of the foot are a major cause of diabetic foot ulcerations.

Especially those people with diabetes who have developed peripheral sensoric neuropathy are considered to be at risk of developing foot ulcers. With peripheral sensoric neuropathy the nerve endings in the feet are affected, resulting in a loss of sensation and proprioception. Repetitive stresses at the location of the elevated pressures, due to for instance walking, can cause small ulcers . These ulcers continue to grow and get infected as they remain unnoticed because of the loss of sensation. At a certain point the infection reaches the bone, resulting in infection of the bone, which is better known as osteomyelitis, and eventually amputation can be needed.

Diabetic foot ulcers can be prevented by reducing the plantar pressures that are too high. In daily practice special footwear such as custom-made insoles and rocker profile shoes are commonly used to reduce plantar pressure. However, the design of these insoles and rocker profile shoes are mainly based on the experience of the prescribing specialist and orthopaedic shoe technician. This leads to a large variety of results and sometimes to insufficient offloading of the foot. Even when the insole or rocker profile shoe initially is effective, over time the location of the pressure spots can shift due to changes of the foot, resulting in poor offloading and putting the person at risk again of developing an ulcer.

The work in this thesis aimed to overcome the problems with the current offloading footwear and includes the design and evaluation of an adjustable rocker profile and a self-adjusting insole.

Chapter 1 provides a general introduction, describing the main problems and the general outline of this thesis. **Chapter 2** contains the analysis phase for the development of the concepts. The analysis phase is used to get a better understanding of the main problems and provides the demarcation of this thesis as it addresses the design goals, design assignments, requirements, and function analyses.

While in literature it was often stated that rocker profiles need to be stiffened for optimal offloading, the difference between stiffened (or rigid) and flexible rocker profiles was not yet evaluated. As this could be an interesting parameter for the design of the adjustable rocker profile the effects of rigid and flexible rocker profiles on in-shoe plantar pressures were evaluated in **Chapter 3**. The results showed that rigid rockers resulted in better offloading of the forefoot compared to flexible rocker profiles. However, pressures were more increased at the first toe when walking with rigid rocker profiles compared to walking with flexible rocker profiles.

The adjustable rocker profile concept was introduced and evaluated in **Chapter 4**. In total seven different rocker settings where evaluated in healthy participants. The settings where based on the location of each participant's metatarsal region. Overall different settings of the adjustable rocker profile resulted in a large reduction of plantar pressures. For different areas of the foot some settings showed larger pressure reductions compared to other settings. However, the large variability between subjects also showed that there is no such a thing as one rocker setting that fits all, which shows that the design of a rocker profile should be individualized.

The self-adjusting insole was introduced and evaluated in **Chapter 5**. The self-adjusting insole consists entirely of small elements of which the top surface only lowers when pressures exceed a certain pressure threshold. The threshold of two configurations, a stiff and flexible one, were tested mechanically and in healthy participants to evaluate the functionality of the self-adjusting insole. While the threshold in the stiff configuration was considered too high, and that of the flexible configuration too low, the functionality of the self-adjusting insole and its potential to redistribute pressures was proven.

In **Chapter 6** the effect of combining the adjustable rocker profile and the self-adjusting insole was evaluated, as rocker profiles and insoles are often combined to get the largest pressure reductions. Both the use of only the adjustable rocker profile and the combination of the two concepts showed larger reductions than the use of only the self-adjusting insole. While there were no large differences in pressure reductions between the combination of both concepts and the adjustable rocker profile, it was found that in some individuals the addition of the self-adjusting insole was needed to reach pressures that are considered safe (< 200 kPa).

After multiple studies with healthy participants both concepts were evaluated in participants with diabetic neuropathy, as these people are considered to have the largest risk of developing diabetic foot ulcers. **Chapter 7** describes a case series with four adults who have diabetes and neuropathy and had initial pressures that are considered dangerous (> 200kPa), putting them at risk of developing diabetic foot ulcers. With the combination of the adjustable rocker profile and the self-adjusting insole it was possible to effectively reduce all of these high pressures to below 200 kPa, which is considered safe.

Finally, the outcomes of this thesis are discussed in **Chapter 8** by evaluating the two innovative concepts based on the findings from the previous chapters, to see if the goals, requirements, and functionality as stated in the analysis phase are met. Also, clinical implications, limitations, and future research are discussed.

SAMENVATTING

Wereldwijd zijn er meer dan 422 miljoen mensen met diabetes. Tussen de 25% en 34% van deze mensen krijgt last van een voetzweer, ook wel diabetische voetulcus, genoemd. Deze ulcera zijn zeer gevaarlijk en kunnen uiteindelijk tot complete amputatie van het aangedane been leiden. Eén van de grootste oorzaken van ulcera zijn te hoge drukken onder de voet van mensen met diabetes. Met name zij die perifere sensorische neuropathie hebben ontwikkeld, lopen een groot risico. Bij perifere sensorische neuropathie zijn de uiteinden van de zenuwen in de voeten aangetast. Hierdoor is het gevoel in de voeten vaak sterk verminderd of zelfs afwezig.

De hoge drukken worden herhaaldelijk op de voet uitgeoefend tijdens bijvoorbeeld lopen, wat op den duur kleine wondvorming veroorzaakt. Door het verminderde gevoel blijft de wond onopgemerkt en raakt deze geïnfecteerd. Op een zeker moment zal de infectie het bot bereiken en kan het bot geïnfecteerd raken. Dit is beter bekend als osteomyelitis. Uiteindelijk is amputatie nodig om verdere verspreiding te voorkomen.

Diabetische voetulcera kunnen worden voorkomen door te hoge drukken onder de voet te verlagen. In de huidige praktijk worden op maat gemaakte inlegzolen en schoenen met een afwikkelcorrectie, ook wel rockerprofiel genoemd, voorgeschreven om drukken onder de voet te verlagen. Echter, het ontwerp van zowel de inlegzolen als de rockerprofielen worden voornamelijk gebaseerd op de ervaring en kennis van de behandelend specialist en orthopedisch schoentechnicus. Dit leidt tot veel verschillende resultaten en soms tot onvoldoende drukverlaging. Bovendien verplaatsen de locaties van de drukpunten door veranderingen in de voet. Dit betekent dat zelfs wanneer de drukverlaging initieel voldoende is, de inlegzool of het rockerprofiel door deze veranderingen niet meer voldoende de hoge drukpunten ontlast. Hierdoor heeft de patiënt weer een verhoogd risico op diabetische ulcera.

Het doel van dit proefschrift is dan ook de problemen met de huidige inlegzolen en rockerprofielen te verhelpen door het ontwikkelen en evalueren van twee speciale concepten. Het eerste concept is een instelbaar rockerprofiel, dat gemakkelijk kan worden aangepast wanneer de locaties van de drukpunten veranderen. Het tweede concept is een zichzelf aanpassende inlegzool, waarvan het oppervlakte profiel automatisch verandert op de

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locaties waar de drukken te hoog zijn. Beide concepten zijn eerst afzonderlijk en vervolgens gecombineerd getest in gezonde vrijwilligers en in mensen met diabetes en neuropathie.

Hoofdstuk 1 bevat de algemene introductie van dit proefschrift. In dit hoofdstuk worden de problemen in meer detail besproken. In **Hoofdstuk 2** wordt de analysefase voor de ontwikkelde concepten beschreven. De analysefase wordt bij het ontwikkelen van nieuwe producten gebruikt om de problemen gedetailleerd in kaart te brengen en de doelen vast te stellen. Ook wordt hier de ontwerpopdracht afgebakend en worden de eisen voor de concepten en de gewenste functionaliteit van de concepten omschreven.

In literatuur over rockerprofielen is vaak beschreven dat rockerprofielen verstijfd moeten worden voor een optimaal drukverlagend effect. Het daadwerkelijke verschil in drukverlaging tussen stijve en flexibele rockers was nog niet getest. Aangezien dit een belangrijke toevoeging kon zijn voor het ontwerp van het instelbare rockerprofiel, zijn deze verschillen in kaart gebracht in **Hoofdstuk 3**. De resultaten toonden aan dat, vergeleken met flexibele rockerprofielen, stijve rockerprofielen inderdaad tot meer drukverlaging onder de voorvoet leidden. Echter, ook bleek dat rockerprofielen in het algemeen leidden tot drukverhoging onder de grote teen, maar dat deze drukverhoging lager was in flexibele rockerprofielen dan in stijve rockerprofielen.

Het instelbare rockerprofiel-concept wordt geïntroduceerd en voor het eerst getest in **Hoofdstuk 4**. In dit hoofdstuk worden de drukken onder de voet gemeten als gezonde vrijwilligers met zeven verschillende instellingen (gebaseerd op hun eigen voeten) lopen. Over het algemeen resulteerde het lopen met het instelbare rockerprofiel tot grote drukverlagingen onder de voeten. Voor bepaalde gebieden onder de voet zorgden sommige rocker-instellingen voor meer drukverlaging dan andere. Echter, de grote variabiliteit tussen proefpersonen toonde aan dat het ontwerp van een rockerprofiel zeer persoonsgebonden is en er niet zoiets is als één algemene rockerprofiel-setting die werkt voor iedereen.

Het zichzelf aanpassende inlegzool-concept wordt geïntroduceerd en getest in **Hoofdstuk 5**. De zichzelf aanpassende inlegzool bestaat uit ongeveer 100 kleine elementen waarvan het oppervlak omlaag beweegt wanneer drukken boven een bepaalde grenswaarde komen. De grenswaarde van

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twee configuraties zijn zowel mechanisch als tijdens het lopen getest om zo de functionaliteit van het concept te onderzoeken.

In **Hoofdstuk 6** is het drukverlagende effect getest van de combinatie van beide concepten. Dit is getest omdat in de huidige praktijk rockerprofielen en inlegzolen vaak worden gecombineerd om een zo hoog mogelijke drukverlaging te bereiken. Zowel het instelbare rockerprofiel alleen als de combinatie van beide concepten resulteerden in grotere drukverlagingen dan wanneer men alleen liep met de zichzelf aanpassende inlegzool. Ondanks dat de verschillen tussen het gebruik van het instelbare rockerprofiel en de combinatie van beide concepten op groepsniveau niet groot waren, bleek het voor sommige proefpersonen nodig om het instelbare rockerprofiel te combineren met de zichzelf aanpassende inlegzool om zo tot drukken onder de voet te komen die als veilig worden verondersteld (< 200 kPa).

Na meerdere studies waarin de concepten zijn getest in gezonde vrijwilligers, beschrijft **Hoofdstuk 7** een studie waarin vier vrijwilligers met diabetische neuropathie de nieuwe concepten gebruiken. Alle vier hadden initieel te hoge drukken (> 200kPa) onder de voeten, waardoor ze een groot risico liepen op het ontwikkelen van ulcera. Met de combinatie van het instelbare rockerprofiel en de zichzelf aanpassende inleg zool was het mogelijk om deze drukken te verlagen tot onder 200 kPa, wat als veilig wordt beschouwd.

Tot slot zijn de uitkomsten van dit proefschrift besproken in **Hoofdstuk 8**. Hier zijn de twee innovatieve concepten geëvalueerd aan de hand van de bevindingen uit de voorgaande hoofdstukken om zo te bepalen of ze voldoen aan de doelen, eisen en functionaliteit die zijn opgesteld in de analysefase. Ook zijn hier de klinische implicaties, beperkingen van de concepten en mogelijkheden voor toekomstig onderzoek besproken.

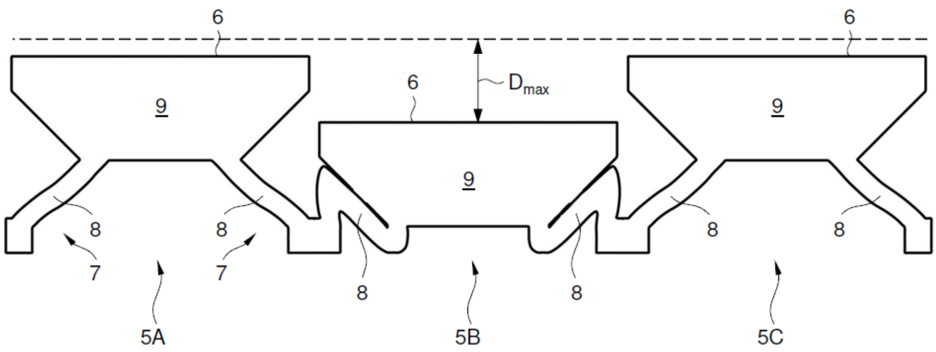
PATENT SELF-ADJUSTING INSOLE

Title: Insole for reducing peak pressures under a foot.

Abstract

The invention provides an insole (1) comprising a plurality of supporting elements (5A, 5B, 5C) distributed over the insole surface for resiliently supporting a foot. Each supporting element comprises a main supporting portion (9) having a narrowing outer shape, and a widening circumferential buckling wall (7) designed to have a buckling behaviour such that: (i) the buckling wall collapses in reaction to a condition in which an external compressive force exceeds a first force threshold (F1); and (ii) if thus being collapsed, the buckling wall resiliently expands in reaction to a condition in which said external compressive force falls below a second force threshold (F2), which is lower than the first force threshold. In use the insole provides a highly effective dynamically self-adjusting pressure distribution reducing peak pressures under a foot, dynamically when the patient walks. In addition, the insole is compact, noncomplex, easy to produce, durable and reliable.

Fig. 4



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The invention relates to an insole for reducing peak pressures under a foot. In the present context it is noted that the term “insole”, as used throughout the present document, may refer to a removable or fixed inner sole of a boot or shoe.

Reducing peak pressures under feet of various people may be desirable for various reasons. It is, for example, particularly desirable for people with diabetes. The reason is that high peak pressures under the feet of people with diabetes can result in diabetic foot ulcers. These ulcers may eventually lead to (partial) amputation of the affected lower limb. Keeping peak pressures below 200 KPa prevents ulcerations.

Custom made insoles are commonly used. In the best situation these are based on a one time pressure measurement. Production processes like 3D printing and CAD have helped with decreasing production costs of these insoles. However, over time pressure spots change due to changes in the foot structure and the insole does not adapt to these changes.

US2017348181A1 discloses an insole, which actually does adapt to changes in the foot structure over time. In fact, the insole known from US2017348181A1 even effectively adapts to changes in pressure spots, dynamically when the patient walks. This known insole is capable of changing along when pressure spots change during walking. However, this known insole is very complex, as well as very expensive. The reason is that this known insole has a layer of many modules, wherein each module has many co-operating parts and aspects, such as a deformable cushion with a cavity, a valve, a tank, a pressure sensor, and a feedback loop.

It is further noted that WO 2018/115874 A1 discloses an insole according to the pre-characterizing portion of appended independent claim 1 of the present disclosure.

It is an object of the present invention to provide at least an alternative insole for reducing peak pressures under a foot, wherein the insole is effective to adapt to changes in pressure spots, dynamically when the patient walks, and wherein the insole is less complex and less expensive than the insole

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known from the above-mentioned US2017348181A1.

For that purpose, the invention provides an insole according to the appended independent claim 1. Preferable embodiments of the invention are provided by the appended dependent claims 2-7.

Hence, the invention provides an insole for reducing peak pressures under a foot, wherein the insole has an insole surface in accordance with a width direction and a length direction of the insole, and wherein the insole comprises a plurality of resilient supporting elements, which are distributed over the insole surface for resiliently supporting a foot in a supporting direction, which is transverse to the insole surface, and wherein, for each supporting element of said plurality of supporting elements, the supporting element has an undeformed condition, from which the supporting element is resiliently deformable under influence of an external compressive force, which is exerted on the supporting element in the supporting direction, the supporting element having a supporting surface for receiving said external compressive force, and wherein the supporting element returns into said undeformed condition in reaction to a condition in which said external compressive force vanishes, and wherein the supporting element comprises a resiliently collapsable buckling part designed to have a buckling behaviour such that:

- the buckling part resiliently collapses in the supporting direction in reaction to a condition in which said external compressive force exceeds a first force threshold, and,

- if thus being collapsed, the buckling part resiliently expands in the supporting direction in reaction to a condition in which said external compressive force falls below a second force threshold, which is lower than the first force threshold,

wherein, as seen in said undeformed condition of the supporting element, the buckling part of the supporting element is formed by an elastically deformable circumferential buckling wall, which is extending circumferentially around a central axis of the supporting element, said central axis of the supporting element being parallel to the supporting direction, and

characterized in that,

as seen in said undeformed condition of the supporting element, and as seen in at least one cross-sectional plane containing said central axis of the supporting element:

- the supporting element further comprises a main supporting portion, wherein said supporting surface is an outer surface of the main supporting portion,

- the main supporting portion in at least a sub-range along said central axis has a narrowing outer shape, such as for example a frusto-conically narrowing outermost shape, as seen in a direction away from said supporting surface,

- the circumferential buckling wall is on a side of the main supporting portion facing away from said supporting surface, and

- the circumferential buckling wall in at least a sub-range along said central axis is widening, such as for example conically widening, as seen in a direction away from said supporting surface.

It is noted that the terms “resilient” and “resiliently”, as used throughout the present document in relation to the above-mentioned supporting element, generally refer to the ability of the supporting element to automatically spring back into shape after being compressed in the above-mentioned supporting direction. Said springing back is occurring towards the above-mentioned undeformed condition of the supporting element and is based on spring force provided by the supporting element itself.

It is further noted that the term “buckling”, as used throughout the present document in relation to the above-mentioned supporting element, more particularly as used in relation to the above-mentioned resiliently collapsable “buckling” part having the above-mentioned “buckling” behaviour, is to be understood to mean: angularly bending as a result of a locally abruptly lower bending stiffness of the supporting element.

The foot of the user will exert pressure on the insole, the pressure being distributed over the total number of supporting elements that are present. The resulting pressure distributed over the surface of an individual supporting element results in a compressive force proportional to the pressure and surface area of the supporting element. This compressive force causes the supporting element to buckle.

As will be readily appreciated from the more detailed example of the drawing figures discussed further below, the resiliently collapsable buckling part with its buckling behaviour can be noncomplex, easy to produce, durable and reliable.

The key features of the insole according to the invention are:

- the plurality of the above-mentioned supporting elements distributed over the insole surface, in combination with

- the fact that each supporting element has the above-mentioned resiliently collapsable buckling part having the above-mentioned collapsing and expanding buckling behaviours in dependence of how the external compressive force behaves relative to the above-mentioned first and second force thresholds, and in combination with

- the above-mentioned narrowing outer shape of the main supporting portion and the above-mentioned widening circumferential buckling wall.

Thanks to these key features local peak pressures are effectively prevented, since one or more of the collapsable buckling parts of one or more of the supporting elements will immediately collapse in case the external compressive force exceeds the first force threshold. Thanks to the collapsing of the buckling part(s) concerned high pressures are automatically prevented at the supporting element(s) concerned. At the same time a larger number of neighbouring supporting elements in unison will take over the load from the supporting element(s) concerned. Hence, the insole according to the invention automatically and dynamically prevents local peak pressures by redistributing the pressures over a larger number of neighbouring supporting elements. In other words, the insole according to the invention provides a highly effective dynamically self-adjusting pressure distribution for reducing peak pressures under a foot. Thanks to the above-mentioned narrowing outer shape of the main supporting portion and the above-mentioned widening circumferential buckling wall, the major feature of the invention, i.e. the supporting element as a whole, is realized in a compact, noncomplex, nonexpensive and reliable manner.

In a preferable embodiment of the invention, said plurality of resilient supporting elements is an integrally manufactured one-piece structure. Such an integrally manufactured one-piece structure further contributes to the noncomplex and/or nonexpensive character of the insole. The one-piece structure may for example be made by a 3D printer. However, many various other manufacturing techniques are available as well, for example various 3D layerwise manufacturing technologies, injection moulding technologies, etc.

In further preferable embodiments of the invention,

- an external pressure exerted on the supporting surface of the supporting element and a first pressure threshold for said external pressure are defined as to proportionally correspond, in terms of uniform pressure distribution over the supporting surface, to the external compressive force exerted on the supporting element and the first force threshold, respectively, and

- said first pressure threshold is higher than 100 KPa and lower than 300 KPa; more preferably higher than 140 KPa and lower than 250 KPa; and yet more preferably higher than 180 KPa and lower than 200 KPa. Depending on the circumstances, these values of the first pressure threshold may reduce peak pressures under a foot to effective levels for preventing various foot problems, such as for example diabetic foot ulcers.

In further preferable embodiments of the invention, the second force threshold is higher than 10% of the first force threshold and lower than 95% of the first force threshold; more preferably higher than 20% of the first force threshold and lower than 85% of the first force threshold; and yet more preferably higher than 30% of the first force threshold and lower than 75%

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of the first force threshold.

Making designs choices so as to obtain values of the second pressure threshold within the above-mentioned ranges, may, depending on the circumstances, contribute to obtaining a favorably even pressure distribution under a foot as seen dynamically when the patient walks. The closer the second pressure threshold is to the first pressure threshold, the sooner the supporting elements will tend to expand again after being collapsed.

In another preferable embodiment of the invention the circumferential buckling wall in collapsed condition of the buckling part is received against the narrowing outer shape of the main supporting portion.

This further contributes to obtaining a compactly collapsing buckling part of the supporting element.

In another preferable embodiment of the invention the main supporting portion is a solid portion of the supporting element in the sense of not being hollow and not containing spaces or gaps.

Such a solid portion further contributes to a favourable deformation behaviour of the supporting element, and it also contributes to a stable supporting behaviour as provided by the supporting element.

In another preferable embodiment of the invention:

- transverse outermost boundary contours of the supporting element are defined as outermost boundary contours of the supporting element, respectively, as seen at least in said undeformed condition of the supporting element, and as seen in cross-sectional planes, which at different positions along said central axis, respectively, are transverse to said central axis, and

- wherein at least one of said outermost boundary contours, and preferably all of said outermost boundary contours, of the supporting element has/have an hexagonal shape.

The hexagonal shape provides the following advantages for providing predictable and reproducible buckling behavior of the supporting elements. The hexagonal shape allows for a maximum of six neighboring elements for each supporting element as opposed to for example a square shape where only a maximum of four neighboring elements may be achieved. In this manner the hexagonal shape advantageously maximizes the amount of neighboring elements that can take over the load from a supporting element, the hexagonal shape thus optimally redistributes the pressure over said neighboring supporting elements.

The hexagonal shape also allows for an even distance between the outermost boundary contours of adjacent supporting surfaces thus providing a more uniform surface for more effectively redistributing the pressure, as opposed to for example a round shape which would leave more space in-between adjacent supporting elements.

Furthermore, the hexagonal shape advantageously allows for the largest number of supporting elements distributed over het insole surface, thus maximizing the amount of supporting elements on the insole

The above-mentioned aspects and other aspects of the invention will be apparent from and elucidated with reference to the embodiments described hereinafter by way of non-limiting examples only and with reference to the schematic figures in the enclosed drawing.

Fig. 1 shows, in a perspective view, an example of an embodiment of an insole according to the invention, wherein the supporting elements of the insole are in their undeformed conditions.

Fig. 2 separately shows, in a perspective view, one of the plurality of resilient supporting elements of the insole of Fig. 1, wherein the shown supporting element is in its undeformed condition.

Fig. 3A shows the supporting element of Fig. 2 in its undeformed condition, however this time in a cross-sectional plane which contains the central axis of the supporting element.

Fig. 3B shows the situation of Fig. 3A again, however this time in a deformation condition of the supporting element in which an external compressive force is exerted on the supporting element in the supporting direction, wherein the external compressive force is lower than the above-mentioned first force threshold, so that the buckling part of the supporting element has not yet collapsed in the supporting direction.

Fig. 3C shows the situation of Fig. 3B again, however this time in a condition in which said external compressive force exerted on the supporting element has exceeded said first force threshold, so that the buckling part of the supporting element has collapsed in the supporting direction.

Fig. 4 separately shows three mutually adjacent ones of the plurality of resilient supporting elements of the insole of Fig. 1, in a cross-sectional plane which contains the central axes of the three supporting elements, wherein the leftmost and rightmost of the three supporting elements are in the deformation condition of Fig. 3B, while the middle one of the three supporting elements is in the deformation condition of Fig. 3C.

Fig. 5 shows a qualitative force/displacement graph, which is typical for a supporting element, such as the specific supporting element of Fig. 2, wherein the graph depicts, for each considered standstill displacement of the supporting element, the resilient reaction force provided by the supporting element when balanced by an oppositely directed equal external compressive force exerted on the supporting element at each considered standstill displacement, respectively.

Fig. 6 shows a full-line graph and a broken-line graph, both as a function of time, wherein the full-line graph is an example of a qualitative force/time graph during a gait cycle performed by a person, the full-line graph qualitatively indicating an imposed external compressive force exerted on a supporting element, such as the specific supporting element of Fig. 2, as a function of time, and wherein the broken-line graph qualitatively indicates the correspondingly resulting displacement of the supporting surface of the supporting element as a function of time during said gait cycle.

The reference signs used in Figs. 1-6 are referring to the above-mentioned parts and aspects of the invention, as well as to related parts and aspects, in the following manner.

1 ------------------------	insole
2 ------------------------	width direction
3 ------------------------	length direction
4 ------------------------	supporting direction
5, 5A, 5B, 5C --------	supporting element
6 ------------------------	supporting surface
7 ------------------------	collapsable buckling part
8 ------------------------	circumferential buckling wall
9 ------------------------	main supporting portion
10 ----------------------	central axis
F_1 ----------------------	first force threshold
F_2 ----------------------	second force threshold
D_{max} --------------------	maximum displacement of the supporting surface (as seen relative to the undeformed condition of the supporting element).

Based on the above introductory description, including the brief description of the drawing figures, and based on the above-explained reference signs used in the drawing, the shown examples of Figs. 1-6 are for the greatest part readily self-explanatory. The following extra explanations are given.

The insole 1 illustrated by Figs. 1-6 is an insole according to each of the appended independent claims 1-7.

As seen in Fig. 1, the insole 1 has a large plurality of mutually identical supporting elements, generally indicated by the reference numeral 5. Three mutually adjacent ones of these identical supporting elements 5 have more specifically been indicated by the reference numerals 5A, 5B, 5C, respectively. These are the three supporting elements 5A, 5B, 5C which are also shown in the cross-sectional plane of Fig. 4. In Fig. 1 it is further seen that the insole 1 of Fig. 1 further has a number of supporting elements, which are different from said mutually identical supporting elements 5. These different supporting

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elements are located along the outer circumferential boundary edge of the insole 1. In fact these different supporting elements are truncated versions of the supporting elements 5.

In the shown example all supporting elements of the insole 1 are interconnected with one another via the circumferential buckling walls 8 of their collapsable buckling parts 7 in a manner as shown in Fig. 4, thereby forming the insole 1 as an integrally manufactured one-piece structure. In fact, the integrally manufactured one-piece insole 1 has been manufactured by means of a 3D-printer.

Figs. 2-4 show the above-mentioned narrowing outer shape of the main supporting portion 9 of the supporting element 5, as seen in a direction away from the supporting surface 6. More specifically it is seen that, in the shown example, said narrowing outer shape is a frusto-conically narrowing outermost shape.

Figs. 2-4 further show that the circumferential buckling wall 8 is widening in a manner as mentioned above. More specifically it is seen that, in the shown example, the circumferential buckling wall 8 is conically widening, as seen in a direction away from the supporting surface 6.

As seen in Figs. 3-4, the conically widening circumferential buckling wall 8, at least in the undeformed condition of the supporting element 5, is defining a recess of the supporting element 5. The main supporting portion 9, on the other hand, is a solid portion of the supporting element 5 in the shown example.

Furthermore, Figs. 1-2 show the above-mentioned hexagonal shapes of the above-mentioned outermost boundary contours of the supporting element 5. More specifically, in the shown example said hexagonal shapes of the outermost boundary contours are occurring along the entire extension range of the supporting element 5 along the central axis 10.

Figs. 3A-3C are illustrating the deformation behaviour of the supporting element 5, including the buckling behaviour of the collapsable buckling part 7, under influence of external compressive forces exerted on the supporting surface 6 of the supporting element in the supporting direction. The undeformed condition of the supporting element 5 as shown in Fig. 3A corresponds to a situation in which the external compressive force is absent.

The condition of the supporting element 5 as shown in Fig. 3B corresponds to a situation in which the external compressive force is present, but does not exceed the first force threshold F_1, so that the buckling part 7 of the supporting element has only been deformed slightly, but has not yet collapsed. Accordingly, in Fig. 3B it is seen that the supporting surface 6 has been only slightly displaced relative to its position (indicated by a broken line) that would correspond to the undeformed condition of the supporting element 5.

The condition of the supporting element 5 as shown in Fig. 3C corresponds to a situation in which the external compressive force is present, and has exceeded the first force threshold F_1, so that the buckling part 7 of the supporting element has fully collapsed. That is, in Fig. 3B it is seen that the supporting surface 6 has been displaced over the maximum displacement D_{max} relative to its position (indicated by a broken line) that would correspond to the undeformed condition of the supporting element 5.

If, starting-off from the collapsed situation shown in Fig. 3C, the external compressive force would fall below the second force threshold F_2 (which is lower than the first force threshold F_1), the buckling part 7 would resiliently expand in such manner that the supporting element 5 would attain a deformation condition similar to that shown in Fig. 3B, or, if the external compressive force would fully vanish, the undeformed condition of Fig. 3A.

Reference is now made to Fig. 5 in order to further explain the deformation behaviour of the supporting element 5, including the buckling behaviour of the collapsable buckling part 7, under influence of external compressive forces exerted on the supporting surface 6 of the supporting element in the supporting direction.

As already mentioned in the introduction, the resilient supporting element 5 has the ability to automatically spring back into shape after being compressed in the supporting direction. Said springing back is based on spring force provided by the supporting element itself. In that sense, the supporting element 5 is for example comparable with a compression spring. A compression spring has a “spring constant”, which defines a linear relationship between external compressive force and displacement. The resilient supporting element of the insole of the present invention, on the other hand, has a totally different relationship between external compressive force and displacement. This is illustrated by Fig. 5, wherein the horizontal axis depicts the displacement of the supporting surface 6 of the supporting element 5, between 0 millimeter and D_{max}, and wherein the vertical axis depicts the involved external compressive force, between 0 Newton and F_1.

Fig. 5 shows that at the start of deforming the supporting element 5, there is a more or less linear relationship between external compressive force and displacement. Next, when the external compressive force reaches the first force threshold F_1, the collapsable buckling part 7 starts to collapse, meaning that the resilient reaction force of the supporting element 5 drastically decreases in combination with a drastically increased displacement, eventually upto the maximum displacement D_{max}. To maintain the maximum displacement D_{max}, it suffices that the external compressive force is higher than or equal to the second force threshold F_2.

It is noted that, in the shown example, the first and second force thresholds F_1 and F_2 are dependent on various design choices of the supporting element 5. For example, in the shown example it has appeared that these first and second force thresholds F_1 and F_2 are highly influenceable by the wall thickness of the circumferential buckling wall 8, as well as by the angle between the circumferential buckling wall 8 and the central axis 10 as important design parameters.

Reference is now made to Fig. 6 in combination with Fig. 4. In Fig. 6 the full-line graph could for example indicate an imposed external compressive force exerted on the supporting element 5B of Fig. 4 during a gait cycle

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performed by a person, wherein the broken-line graph of Fig. 6 indicates the correspondingly resulting displacement of the supporting surface 6 during said gait cycle. From Fig. 6 it is seen that the supporting element 5B of Fig. 4 is in fully collapsed condition during a major part of the gait cycle. Fig. 4 illustrates that, when the supporting element 5B is collapsed, the neighbouring supporting elements, such as the elements 5A and 5C of Fig. 4, in unison will take over the load from the supporting element 5B. Accordingly, Figs. 4 and 6 make clear that local peak pressures under a foot are effectively prevented thanks to the insole 1, since one or more of the collapsable buckling parts of one or more of the supporting elements of the insole 1 will immediately collapse in case the external compressive force exceeds the first force threshold. Thanks to the collapsing of the buckling part(s) concerned high pressures are automatically prevented at the supporting element(s) concerned. At the same time a larger number of neighbouring supporting elements in unison will take over the load from the supporting element(s) concerned. Hence, the insole according to the invention automatically and dynamically prevents local peak pressures by redistributing the pressures over a larger number of neighbouring supporting elements. In other words, the insole according to the invention provides a highly effective dynamically self-adjusting pressure distribution for reducing peak pressures under a foot.

Prototypes of the invention were manufactured by Fused Deposition Modelling 3D printers using thermoplastic polyurethane filament. Each supporting element 5 was manufactured with a height of 9 mm, a supporting surface 6 area of 1.46 cm2, a D_{max} of 3.5 mm. Again, specific pressures over the supporting surface 6 will result in proportional values for the force thresholds. Different values for the main design parameters, said design parameters being wall thickness of the circumferential buckling wall 8, the angle between the circumferential buckling wall 8 and the central axis 10, were manufactured and these resulted in the following example first force thresholds (F_1) and example second force thresholds (F_2) during quasi-static measurements that provided good functionality:

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Wall Thickness	Angle	F_1	F_2
0.90 mm	40˚	14.9 N / 102 kPa	10.8 N / 74 kPa
1.05 mm	40˚	19.3 N / 132 kPa	13.7 N / 94 kPa
1.20 mm	40˚	28.9 N / 198 kPa	19.6 N / 134 kPa
0.90 mm	45˚	11.4 N / 78 kPa	8.1 N / 55 kPa
1.05 mm	45˚	15.4 N / 105 kPa	10.5 N / 72 kPa
1.20 mm	45˚	20.9 N / 143 kPa	15.0 N / 103 kPa

The values shown for F_1 and F_2 are the compressive force measured on the supporting surface, and the corresponding local pressure on the supporting surface at buckling (F_1) and springing back (F_2). It is noted that these example values were identified by the inventors under laboratory conditions as providing good functionality, but other values for the wall thickness of the circumferential buckling wall 8, the angle between the circumferential buckling wall 8 and the central axis 10 may be identified with further development that also provide equal or better functionality.

It is noted that in Fig. 1 the width direction 2 and the length direction 3 of the insole are both depicted as straight linear directions. Generally, however, both the width direction 2 and the length direction 3 may also be curved directions, so that also the insole surface of the insole may generally be a two-dimensionally curved surface. In fact the insole 1 of Fig. 1 is a deformable structure in both said directions.

While the invention has been described and illustrated in detail in the foregoing description and in the drawing figures, such description and illustration are to be considered exemplary and/or illustrative and not restrictive; the invention is not limited to the disclosed embodiments.

For example, in the shown example, the outermost boundary contours of the supporting element 5 have hexagonal shapes. Instead, many various other shapes of such outermost boundary contours are also possible according to the invention, such as circular, oval, or otherwise rounded shapes, or triangular, square, or otherwise piecewise linear shapes, etc.

As a further example it is mentioned that one insole according to the invention may comprise different kinds of the supporting elements, having different shapes, collapsing properties, etc., instead of all the same supporting elements. For example, the different kinds of supporting elements may be located in different zones along the support surface of the insole, respectively. In fact, an insole according to the invention may be designed both as a custom design and as an off-the-shelf design.

It is further noted that an insole according to the invention may not only be beneficial for people with diabetes. It may also be beneficially applied to many various other boots or shoes, such as for example to many various sportsshoes.

Other variations to the disclosed embodiments can be understood and effected by those skilled in the art in practicing the claimed invention, from a study of the drawings, the disclosure, and the appended claims. In the claims, the word “comprising” does not exclude other elements or steps, and the indefinite article “a” or “an” does not exclude a plurality. A single part may fulfill the functions of several items recited in the claims. For the purpose of clarity and a concise description, features are disclosed herein as part of the same or separate embodiments, however, it will be appreciated that the scope of the invention may include embodiments having combinations of all or some of the features disclosed. The mere fact that certain measures are recited in mutually different dependent claims does not indicate that a combination of these measures can not be used to advantage. Any reference signs in the claims should not be construed as limiting the scope.

Claims

The claims will be publicly available through Espacenet medio February, 2021

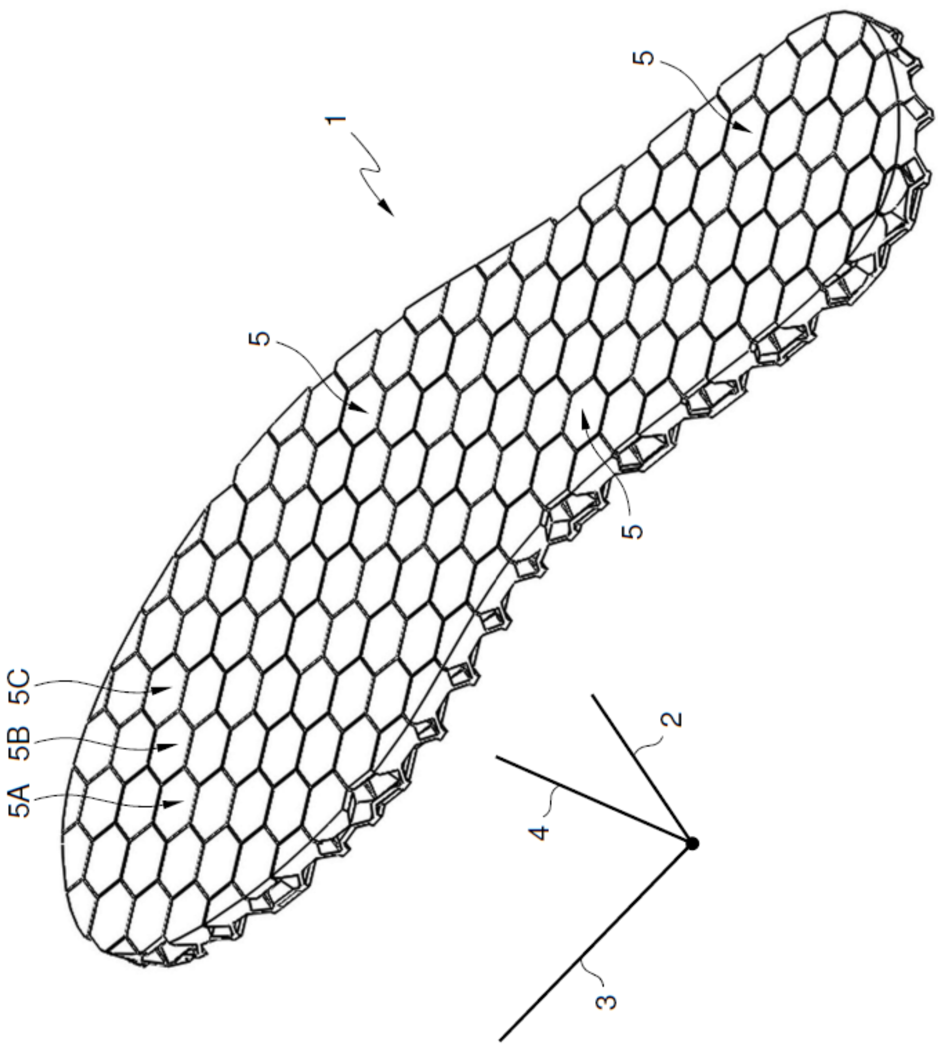

FIG.1

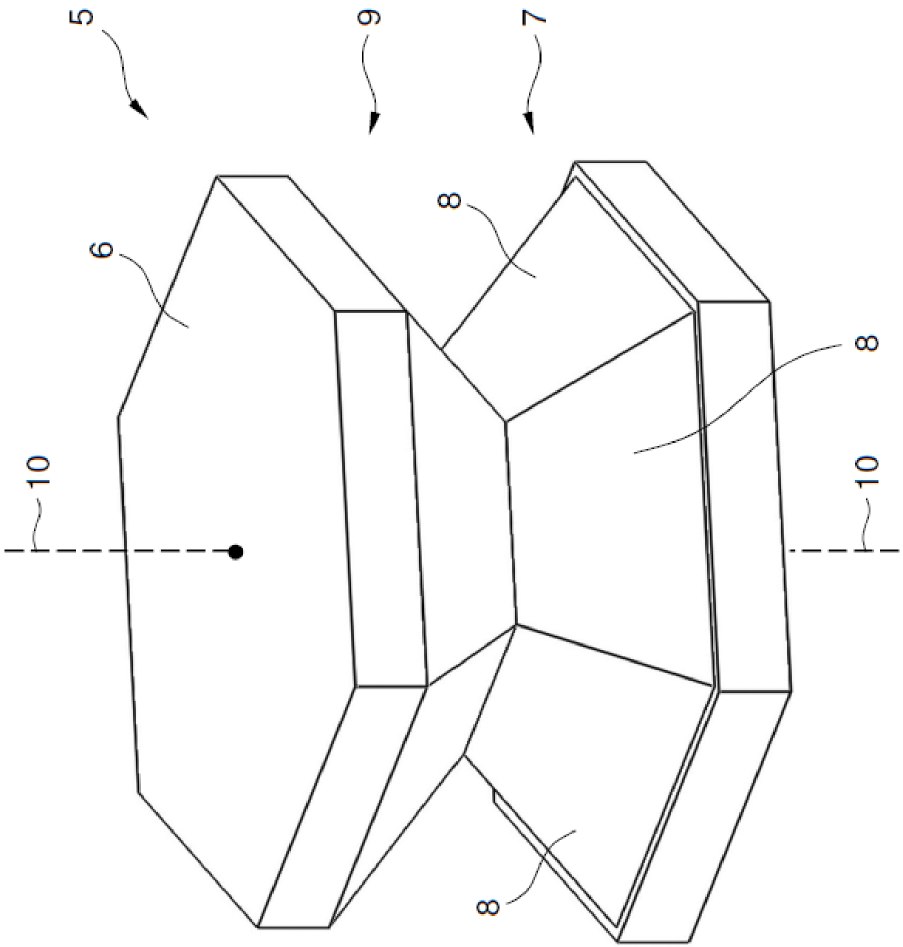

FIG. 2

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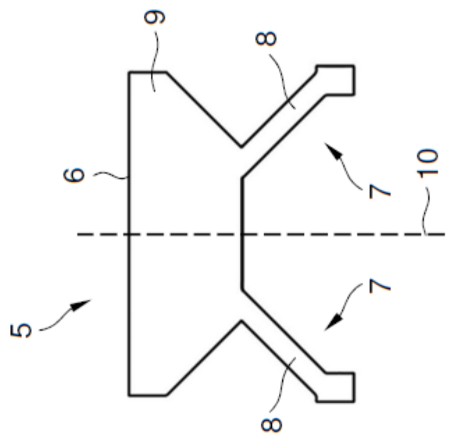

FIG. 3A

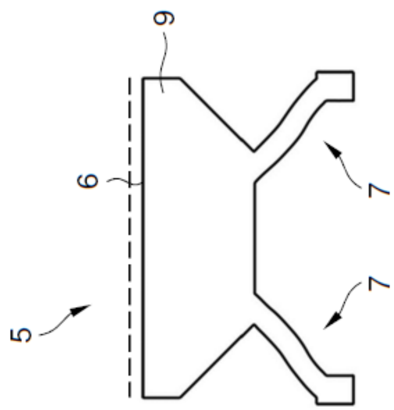

FIG. 3B

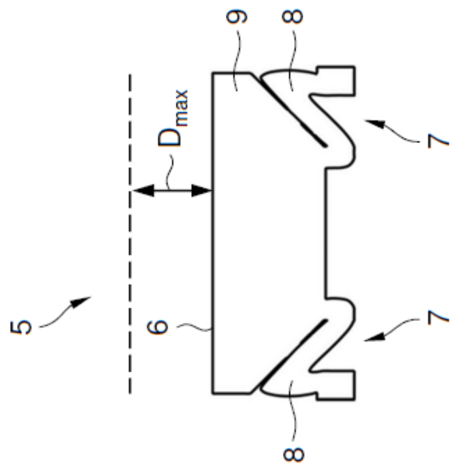

FIG. 3C

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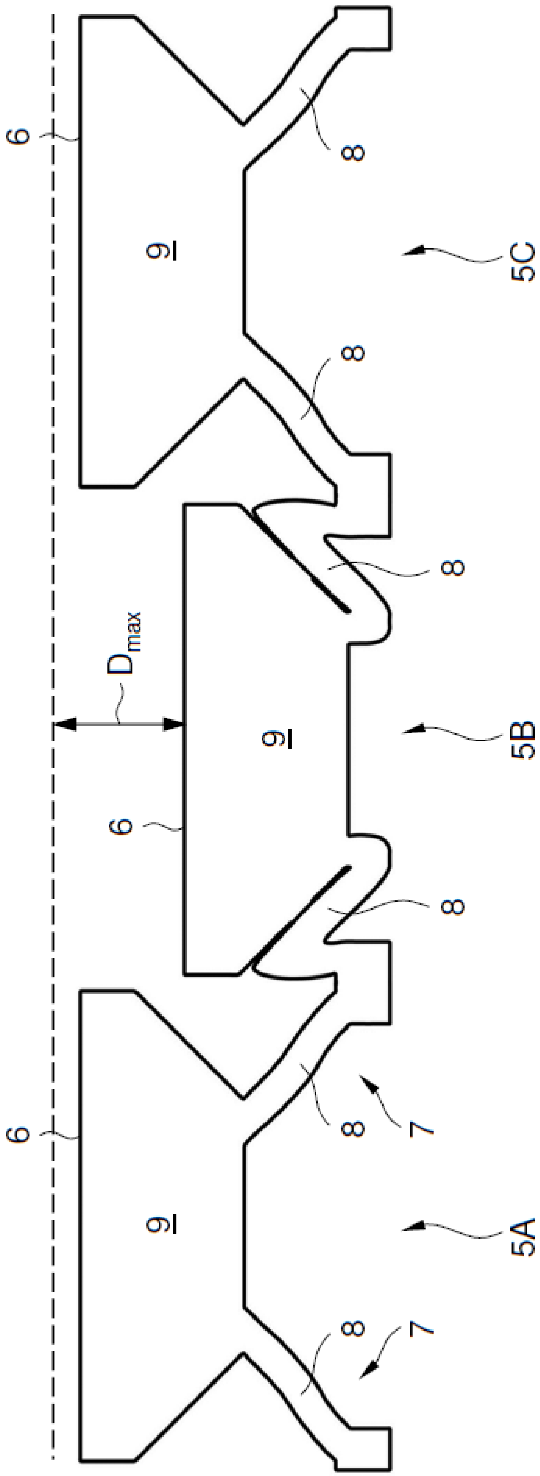

FIG. 4

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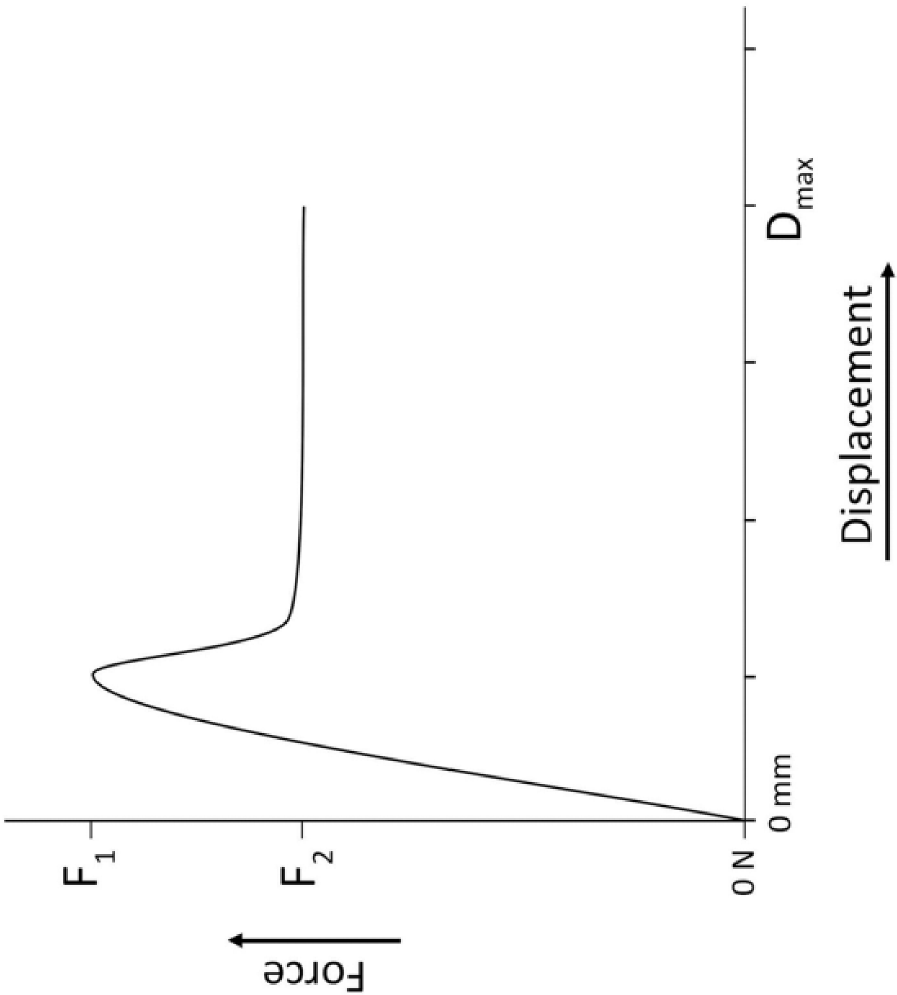

FIG. 5

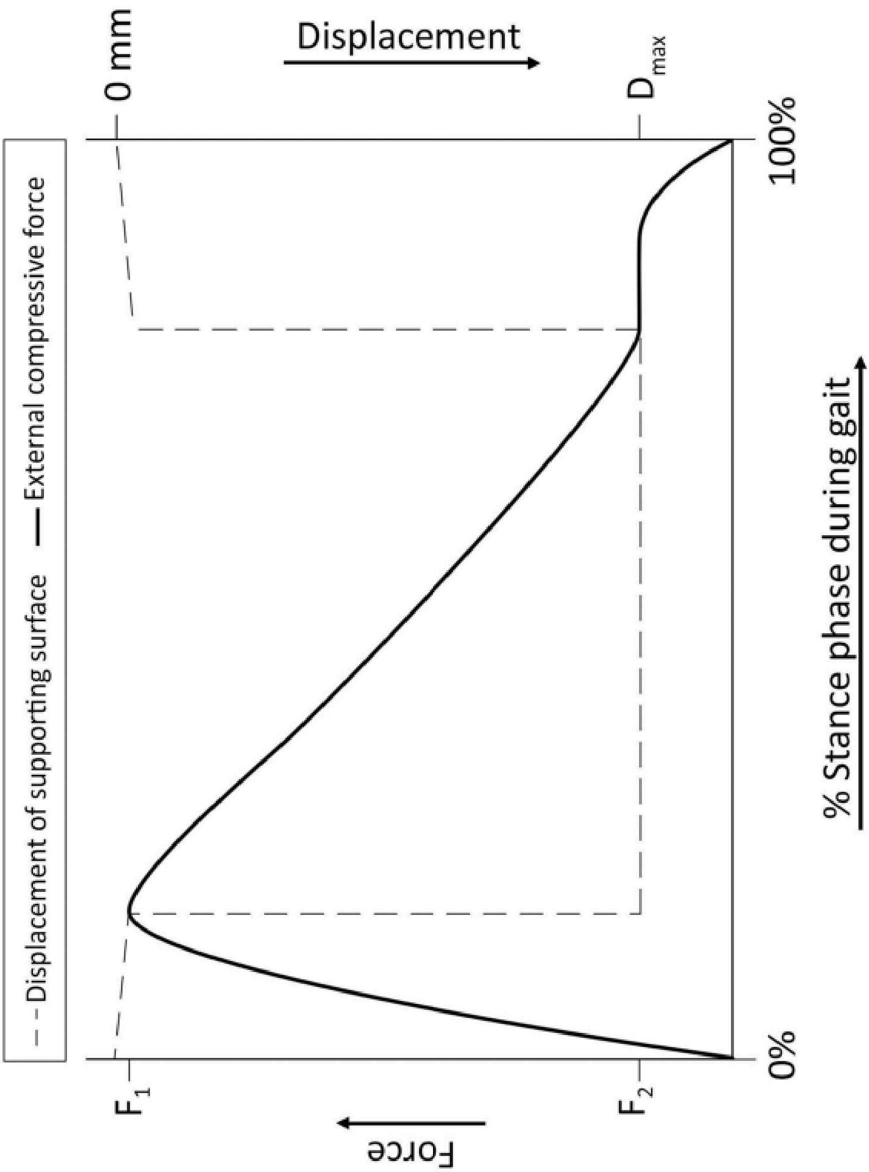
- - Displacement of supporting surface
— External compressive force
Displacement
0 mm
D max
F 1
F 2
Force
0%
100%
% Stance phase during gait

FIG. 6

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ACKNOWLEDGEMENTS

Er zijn veel mensen die direct of indirect hebben bijgedragen aan het voltooien van dit proefschrift; hen wil ik allen enorm bedanken. Een aantal personen wil ik hieronder in het bijzonder bedanken. Allereerst enorm veel dank aan mijn promotoren: **Prof. dr. ir. G.J. Verkerke**, **Prof. dr. K. Postema** en **Dr. J.M. Hijmans**.

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CURRICULUM VITAE

Roy Reints was born in Stadskanaal on March 3rd, 1989. He graduated secondary school in 2008 after which he became a student at the University of Groningen. In 2012 he graduated from the Bachelor Life Science & Technology which was followed by a Master's degree in Biomedical engineering in the beginning of 2015. During the last year of his Master's degree Roy was an intern at the department of Rehabilitation Medicine where he designed an innovative ankle-foot orthosis, which resulted in a patent. Straight after his graduation, he started working as a PhD – candidate at the same department. During his PhD, Roy presented his work at several (inter)national conferences and scientific meetings. In September of 2019 Roy started working at Johnson & Johnson Vision where he now works as Sr. Engineer at the R&D department.

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